CAB-20-MIN-0229.01

Cabinet

Minute of Decision

This is the exhibit marked "**ARB-1**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

COVID-19 Vaccine Strategy

Portfolios **Foreign Affairs / Research, Science and Innovation / Health**

On 18 May 2020, following reference from the Cabinet Social Wellbeing Committee, Cabinet:

1 **noted** that COVID-19 vaccination is currently viewed as a critical platform to support New Zealand to fully re-open its borders and to step down from Alert Level 1 to Alert Level 0;

2 **noted** that the Ministry of Health will undertake immunisation strategy work as vaccine development and testing progresses, and that a working assumption is that New Zealand will seek immunity of at least 80 percent of the population, with an initial focus on vulnerable groups;

3 **agreed** that the government should put in place a COVID-19 vaccine strategy to promote access to a sufficient quantity of a safe and effective vaccine in order to implement the government's preferred immunisation strategy at the earliest possible time;

4 **agreed** that the strategy should contribute to the following outcomes:

4.1 sufficient supply of a safe and effective vaccine to achieve population immunity to COVID-19, affordably;

4.2 protection for population groups at particular risk from COVID-19;

4.3 full cultural, social and economic recovery from the impacts of COVID-19;

4.4 recognition of New Zealand as a valued contributor to global wellbeing and the COVID-19 response;

4.5 New Zealand, Pacific, and global preparedness for response to future disease outbreaks;

5 **agreed** that the vaccine strategy should be guided by the following principles:

5.1 the strategy should be flexible enough to allow for changes of course as international vaccine development programmes progress, and to cope with shifts in the global context;

5.2 the approach needs to hedge against a range of possible outcomes, and the size of the benefit justifies the investment in cost and effort to do this effectively;

5.3 the strategy should integrate and coordinate multiple approaches to make the best use of the tools New Zealand has available, including capacity and expertise outside of government;

5.4 the government needs to engage actively in shaping the global context and contributing to collective efforts, as well as seeking New Zealand's partnerships in support of the strategy;

5.5 New Zealand needs to contribute to the global effort;

6 **agreed** that the strategy should be structured around five inter-related pillars:

6.1 connecting globally to contribute to all aspects of vaccine development, distribution, and use;

6.2 supporting vaccine research that contributes to global efforts, builds relationships, and supports early access to a vaccine;

6.3 developing manufacturing capability in case it is needed to promote supply;

6.4 optimising regulatory approaches to ensure safety, support research, and enable manufacturing;

6.5 using purchasing tools to secure supply where possible and to enhance resilience;

7 **noted** that some early first steps have already been taken and others can be taken early to forward the strategy;

8 **noted** that the government should use New Zealand's full range of diplomatic tools and relationships to advance New Zealand's interests in access to a safe and effective vaccine;

9 **invited** the Minister of Foreign Affairs, Minister of Research, Science and Innovation, and the Minister of Health to report-back to the Cabinet Social Wellbeing Committee during June 2020, and then at least quarterly, on:

9.1 an agreed and funded programme of vaccine research in support of the vaccine strategy;

9.2 actions to support the development of a manufacturing capability in New Zealand and/or contribute to other developments;

9.3 progress with international engagement on and contributions to vaccine development, manufacturing, regulatory, purchase, and distribution, including equitable access;

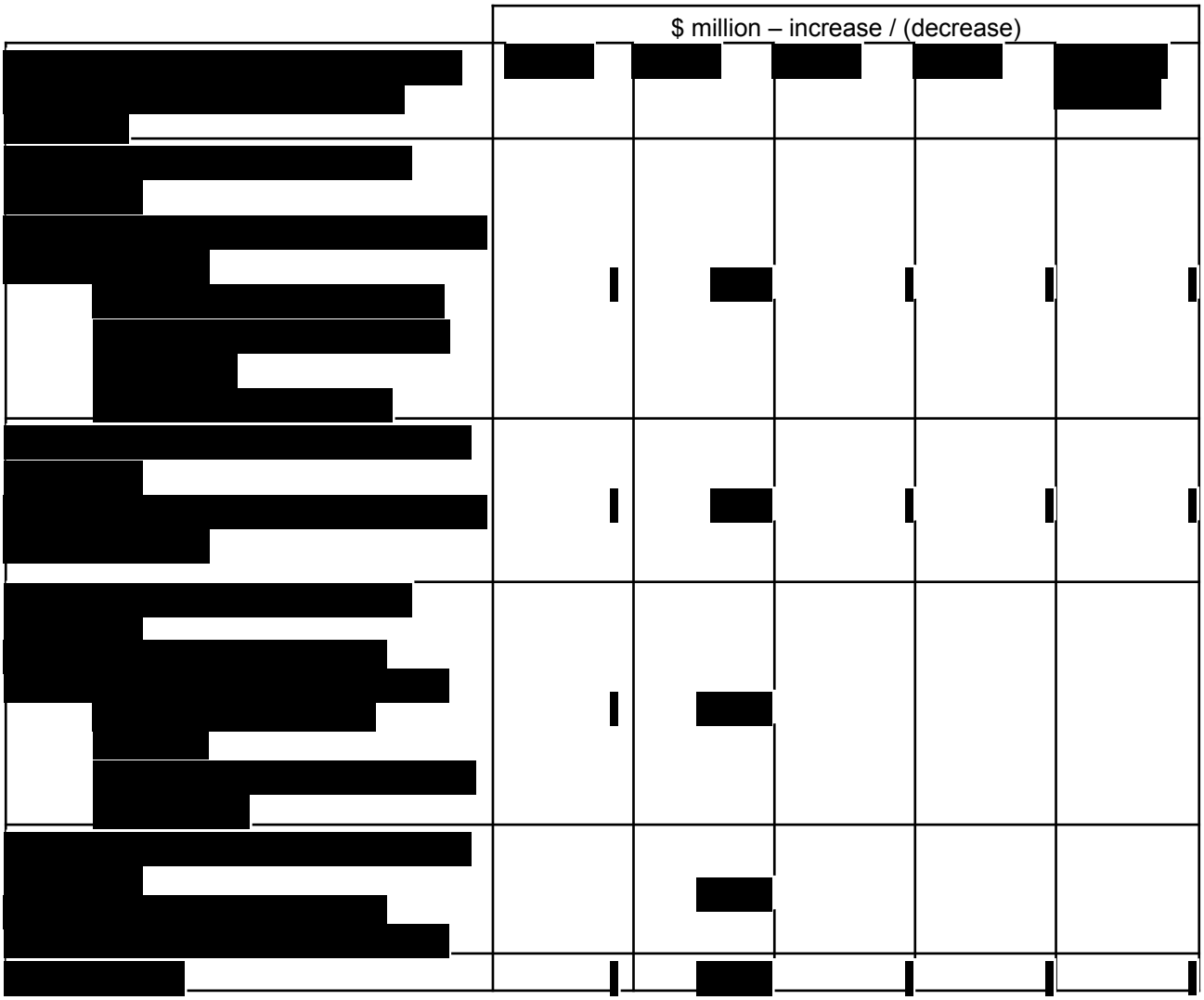
9.4 next steps for the strategy, including the development of a vaccine distribution plan;

10 **noted** that the Ministry of Foreign Affairs and Trade, Ministry of Business, Innovation and Employment, and the Ministry of Health will set up a task force to direct implementation of the strategy;

11 **noted** that the task force will be advised by a scientific and technical advisory group in order to ensure access to a range of views from the scientific community and potential vaccine manufacturers;

12 **agreed** to provide $30 million to support domestic and international research on, and the potential for domestic manufacturing of, a COVID-19 vaccine;

13 **approved** the following changes to appropriations to give effect to the policy decision in paragraph 12 above with a corresponding impact on the operating balance and net core Crown debt:



14 **agreed** that the changes to appropriation for 2020/21 above be included in the 2020/21 Supplementary Estimates, and, in the interim, the increases be met from Imprest Supply;

15 **agreed** that the expenses incurred under paragraph 12 above be charged against the COVID-19 Response and Recovery Fund established as part of Budget 2020.

Michael Webster
Secretary of the Cabinet

Secretary's Note: *This minute replaces SWC-20-MIN-0042. Cabinet amended paragraphs 1 and 4.2.*

CAB-20-MIN-0509

Cabinet

Minute of Decision

Update on the COVID-19 Immunisation Strategy and Programme

Portfolios **COVID-19 Response / Health / Associate Health (Hon Dr Ayesha Verrall)**

On 7 December 2020, Cabinet:

1 **noted** that in August 2020, Cabinet invited a report back on progress towards developing a COVID-19 Immunisation Strategy, including a 'prioritisation framework' (now referred to as the Sequencing Framework) [CAB-20-MIN-0382];

2 **noted** that the paper under CAB-20-SUB-0509 should be read alongside the accompanying papers COVID-19 Vaccine Strategy: Update on Vaccine Purchasing [CAB-20-SUB-0508] and Support for Pacific and Global Vaccine Access and Roll-out [CAB-20-SUB-0504];

3 **agreed** that the government approach to COVID-19 immunisation is guided by the following principles:

3.1 the COVID-19 vaccines we deliver will be free and safe;

3.2 we will sequence the roll-out as COVID-19 vaccines become available;

3.3 the sequencing of access must be needs based;

3.4 we will continue to have strong border settings and roll-out strategy until we are confident that the New Zealand population is sufficiently protected;

4 **noted** that these guiding principles are consistent with the overarching Elimination Strategy principles of equity and wellbeing;

5 **agreed** that the purpose of the COVID-19 Immunisation Strategy is to support the "best use" of COVID-19 vaccines, while upholding and honouring Te Tiriti o Waitangi obligations and promoting equity;

6 **noted** that the COVID-19 Immunisation Programme would be the largest immunisation programme undertaken in New Zealand to date;

7 **noted** that work is well underway to enable the delivery of the COVID-19 Immunisation Strategy and Programme, informed by experience from other immunisation programmes;

COVID-19 Immunisation Programme

8 **noted** that the COVID-19 Immunisation Programme supports the implementation of the Strategy, and includes:

8.1 a plan for communications and engagement with key messages to encourage uptake and build confidence in the immunisation system;

8.2 planning to distribute, manage inventory and schedule immunisation;

8.3 developing the National Immunisations Solution to replace the National Immunisation Register;

8.4 post-market monitoring to enable the Ministry of Health to adapt its approach as it learns more;

9 **noted** that the Ministry of Health will continue engagement fortnightly with the external Immunisation Implementation Advisory Group, which has strong Māori and Pacific representation, on the COVID-19 Immunisation Programme;

10 **agreed** that the Ministry of Health start to engage with other external stakeholder networks on the COVID-19 Immunisation Strategy and Programme before the end of 2020;

11 **noted** that the Ministry of Health is working to ensure that it can successfully implement the COVID-19 Immunisation Programme as soon as a COVID-19 vaccine has regulatory approval and is available for use in New Zealand;

12 **noted** that Medsafe has made arrangements that will enable the regulatory approval process to be as efficient as possible;

Sequencing and decision to use frameworks

13 **agreed** that officials develop a framework on the "decision to use" any approved vaccines available, as there will likely be a number of trade-offs to consider;

14 **noted** that, at least initially, immunisation may need to be sequenced if supply is limited, and that officials have developed a Sequencing Framework to inform this decision, attached in summary as Appendix Three of the submission under CAB-20-SUB-0509;

15 **agreed** that the purpose of the Sequencing Framework is to ensure the right people are vaccinated at the right time with the right vaccine while upholding and honouring Te Tiriti o Waitangi obligations;

16 **agreed in principle** to the current Sequencing Framework, noting that it will be updated to reflect new and emerging evidence;

17 **invited** the Minister of Health to report back by the end of February 2021 on progress with the frameworks for deciding:

17.1 to use a COVID-19 vaccine; and

17.2 how to sequence immunisation as vaccines become available;

Financial recommendations

18 **noted** that updated estimates indicate that the COVID-19 Immunisation Programme costs are now estimated at s 9(2)(f)(iv), s 9(2)(j) up to December 2021, of which $66.3 million has already been drawn down from the Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency;

19 **noted** that the COVID-19 Immunisation Programme costs have been prepared on the assumption that the COVID-19 vaccine product will be free for the New Zealand population;

20 **noted** that officials will provide additional advice in relation to eligibility for COVID-19 immunisation, the approach to any General Practitioner co-payment, and other related matters by the end of February 2021;

21 **noted** the accompanying paper "COVID-19 Vaccine Strategy: Update on vaccine purchasing" [CAB-20-SUB-0508] provides the full estimated fiscal implications across the COVID-19 Vaccine Purchasing and Immunisation Programmes and seeks agreement to the additional funding required.

Michael Webster
Secretary of the Cabinet

Appendix Two: Key principles underpinning the Immunisation Strategy

The table below maps the overarching decision-making principles against the principles that underpin the COVID-19 Immunisation Strategy principles. As noted in the Elimination Strategy, equity is to be prioritised consistently across all levels of the strategic response to COVID-19.

Overarching principles		COVID-19 Immunisation Strategy principles	What this means for the design of the Immunisation Programme	What this means for how we will sequence immunisation
Uphold and honour Te Tiriti o Waitangi	Equity *(Elimination Strategy decision-making principle)*	Equity	Promote equitable outcomes, particularly for Māori, Pacific peoples and disabled people	
		Equal concern	Encourage and enable uptake of safe, free COVID-19 vaccine/s	All people are equally deserving of care and over time will have access to the vaccine
	Wellbeing *(Elimination Strategy decision-making principle)*	Minimise the health, social, economic and cultural harm of COVID-19	Make the process is easy for New Zealanders to encourage uptake, with strong border settings until we are confident that the New Zealand population is protected	Phased roll-out that is needs based, aiming to minimise harm and achieve evidence-based public health benefits from immunisation
		Regional responsibility	Recognise and respond to the unique circumstances of the Realm countries (Tokelau, the Cook Islands, and Niue) and other Pacific nations (Sāmoa, Tonga and Tuvalu), which are included in New Zealand's Vaccine Strategy	
	Legacy	Value	Maximise value, by getting the most from the resources available	Maximise value, by getting the most from the resources available
		Legitimacy	Improve the wider immunisation system and public perceptions of immunisation, and call on appropriate expertise	We always act in the best interests of our populations, we make trade-offs clear, we use robust frameworks and evidence, and call on appropriate expertise

This is the exhibit marked "**ARB-3**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

SENSITIVE

Office of the Minister for COVID-19 Response

Office of the Minister of Health

Office of the Associate Minister of Health

Cabinet

This is the exhibit marked "**ARB-4**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

February 2021 update on the COVID-19 Immunisation Strategy and Programme

Proposal

1 In December 2020, Health Ministers were invited to report back to Cabinet on the COVID-19 Immunisation Strategy [CAB-20-MIN-0509 refers]. In response to this request, this paper:

1.1. summarises key changes in the global and domestic COVID-19 context since the December 2020 Cabinet meeting;

1.2. provides an update on Vaccine Purchasing, the COVID-19 Immunisation Programme, including key timeframes and what we know about vaccine impacts for people and populations; and

1.3. seeks endorsement of the proposed Decision to Use Framework and updated Sequencing Framework to support best use of COVID-19 vaccines, along with advice on related policy issues.

Executive Summary

2 New Zealand has secured a portfolio of COVID-19 vaccines for 14.91 million courses through four Advance Purchase Arrangements (APAs) [CAB-20-MIN-0508 refers].

3 Since December 2020, international developments, specifically the identification of new variants of COVID-19, have increased the importance of the New Zealand COVID-19 Immunisation Programme.

4 6(a) [redacted] and has recently provisionally approved their first COVID-19 vaccine, enabling the initial tranche of vaccines to be rolled out as early as February 2021 to frontline hotel quarantine workers.

5 New Zealand's regulatory process for the Pfizer vaccine is progressing ahead of schedule, and the first shipments are expected from mid-late February 2021. Subject to a regulatory decision by Medsafe and vaccines arriving on schedule, the Ministry of Health is on track to distribute and administer these first shipments of Pfizer vaccines from mid-February 2021.

6 There are a number of key decision points and milestones in February 2021. To avoid delay, we recommend that Joint Ministers (the Prime Minister, Minister of Finance, Minister for COVID-19 Response, Minister of Health, Associate Minister of Health, Minister of Research, Science and Innovation and the Minister of Foreign Affairs) are granted the power to act in order to ensure timely decision making on the COVID-19 Immunisation Programme.

7 To inform these upcoming decisions, the Ministry of Health has developed a draft Decision to Use Framework to optimise delivery of the COVID-19 Immunisation Programme, and the flow on portfolio implications. The Decision to Use Framework will provide a robust process for decisions on how to use COVID-19 vaccines, who to use them for, and when to use them. This paper seeks your agreement to the structure, approach and objectives of the Decision to Use Framework.

8 Cabinet agreed in principle [CAB-20-MIN-0509 refers] to a Sequencing Framework to guide use of the vaccine where supply is limited.

9 Since December 2020, the Sequencing Framework has been updated to reflect the latest evidence and is attached at Appendix One. The objectives of the Sequencing Framework have been updated to reflect uncertainty around the ability for the vaccine to prevent transmission compared to protecting individuals against the disease.

10 Officials will monitor emerging evidence and data to guide our preparations to implement the Sequencing Framework. This will include particular risks faced by certain populations and advice about the effectiveness of vaccines in reducing transmission from technical and scientific experts.

11 On 23 January 2021, New Zealand recorded its first case outside of Managed Isolation and Quarantine Facilities (MIQF) since November 2020. To manage the risk that COVID-19 may re-emerge in communities throughout New Zealand, the Sequencing Framework accounts for how the vaccine will be used given different community transmission scenarios.

12 To support our COVID-19 Elimination Strategy, maintaining strong border settings alongside the COVID-19 Immunisation Programme delivery will be critical until we are confident that the New Zealand population is sufficiently protected from COVID-19.

13 To support maximum uptake of the COVID-19 vaccine, we recommend that publicly funded COVID-19 immunisation is made available to everyone in New Zealand regardless of visa status.

14 A key pillar of the COVID-19 Immunisation Programme is the communications strategy. The overarching purpose of the public communications strategy is to build trust and confidence in the COVID-19 vaccines and the Immunisation Programme to encourage uptake. To support this, we have commissioned market research in New Zealand to better understand attitudes to the COVID-19 vaccines, and how they are changing over time. Our communications strategy will respond to emerging themes from this research. Once the market research is completed and available it will be made publilcly available.

15 This paper will be followed by the Cabinet Paper *Provision of COVID-19 vaccines for the Polynesian countries* on 22 February 2021.

Background

16 COVID-19 vaccines will be critical in the continued response to COVID-19 and protecting the health and wellbeing of New Zealanders, along with existing public health measures.

Cabinet has agreed to a strategy for purchasing COVID-19 vaccines…

17 In May 2020, Cabinet agreed to the COVID-19 Vaccine Strategy [CAB-20-MIN-0382 refers]. The objective is to secure access to sufficient quantities of safe and effective COVID-19 vaccines, in order to implement our preferred COVID-19 Immunisation Programme at the earliest possible time.

18 As previously noted, we are deliberately taking a portfolio approach to manage the risk of vaccine development failure and to support the COVID-19 Immunisation Programme [CAB-20-MIN-0508].

19 Through bilateral agreements, we have secured four vaccine candidates in our portfolio from three leading technology platforms. The table below provides an updated overview of vaccine candidates we have entered Advance Purchase Arrangements (APAs) with (see Appendix Two for details).

Vaccine candidate (vaccine type)	**Courses purchased**
Pfizer/BioNTech (mRNA)	750,000
Janssen (viral vector)	5 million
AstraZeneca (viral vector)	3.8 million
Novavax (protein sub-unit)	5.36 million
Total expected:	14.91 million courses

Note: This table represents advance purchasing arrangements with vaccine suppliers. Details of delivery schedules are yet to be confirmed

20 Additional doses of AstraZeneca and Pfizer vaccines are being sort through the COVAX Facility, however, these have yet to be secured through an APA.

21 Management of COVID-19 Vaccine APAs is transitioning to the Ministry of Health from the Ministry of Business, Innovation and Employment. The Ministry will be supported by expertise of PHARMAC and brought in experience from the private sector (see Appendix Three for more detail).

Since the December 2020 report-back there have been a number of key international developments

22 Other developed and middle-income countries around the world have started immunising their populations against COVID-19 in response to widespread COVID-19 outbreaks in their communities and increasing pressure on their health systems.

23 The recent detection of more infectious strains of COVID-19 has increased the urgency of vaccine roll-out both nationally and globally. With a backdrop of increasing disease incidence and prevalence, the ability to maintain our Elimination Strategy in New Zealand is likely to require maintaining tight restrictions at the border.

24 Due to large global demand for COVID-19 vaccines, supply will be limited in at least the short-term, as vaccine manufacturers scale up production. Some manufacturers are experiencing setbacks that could lead to delays in deliveries. In parallel, other jurisdictions have signalled the potential for export controls. Officials are continuing to regularly engage with pharmaceutical companies and international counterparts to manage surety of vaccine supply.

25 As of December 2020, several jurisdictions including the European Union, United Kingdom, the United States of America, and Canada have issued emergency authorisation for the Moderna, Pfizer-BioNTech and AstraZeneca vaccines. These vaccines have shown successful preliminary results, however long-term outcomes have not been reported for any COVID-19 clinical trials and there are many questions yet to be answered about COVID-19 vaccines.

26 In late January 2021, Australia's medical regulator, the Therapeutic Goods Administration (TGA), provisionally approved the Pfizer/BioNTech COVID-19 vaccine for use in Australians 16 years of age and older. The Australian Government has received advice from Pfizer that delivery of the vaccine is expected in late February, with vaccinations also commencing within these timeframes. If there are delays in shipping or production, the possibility remains that vaccinations could commence in late February 2021.

27 Officials are in regular contact with other partner countries about their vaccine rollout, and the Ministry of Foreign Affairs and Trade (MFAT) is tracking global trends and findings to help inform our immunisation planning. Medsafe is working closely with the TGA in Australia to ensure information is shared as and when it is available to progress our COVID-19 Immunisation Programme along similar timelines.

Over the next four weeks officials anticipate a series of key decisions and milestones for the COVID-19 Immunisation Programme

28 To avoid delay, we recommend that Joint Ministers (the Prime Minister, Minister of Finance, Minister for COVID-19 Response, Minister of Health, Associate Minister of Health, Minister of Research, Science and Innovation and the Minister of Foreign Affairs) are granted the power to act in order to ensure timely decision making on the COVID-19 Immunisation Programme. This means Joint Ministers would have the power to act to make timely decisions on when, for whom and how to use vaccines in

the portfolio, along with making other decisions that may be necessary to support the programme to deliver.

29 The table below highlights the key milestones for the coming month:

Anticipated timeframe (best case)	Milestones	Decision maker
Early February 2021	Regulatory decision on Pfizer	Medsafe
Early February 2021	Decision on Import and Release of Pfizer	Environmental Protective Authority (EPA) [1]
Early February 2021	Decision to use Pfizer	Joint Ministers
Early February 2021	Decisions on the Sequencing Framework	Joint Ministers
Mid-Late February 2021	First Shipment of Pfizer received	Nil
Mid-Late February 2021	Programme Readiness Assessment	Joint Ministers
Mid-late February	Quality Assurance of Vaccines	Pfizer and Ministry of Health
From late February 2021	Initiate Phase 1 implementation of initial supply of vaccines	Ministry of Health

30 Over the next four weeks Joint Ministers will have the opportunity to make choices about how to use the Pfizer vaccine. These decisions will be guided by the Decision to Use Framework in paragraphs 53-61 below.

31 Before any vaccine is used in New Zealand, it needs to be approved as safe and effective by Medsafe (under the Medicines Act 1981). This process is important to provide assurance and transparency to help maintain public confidence that medicines meet acceptable standards of safety, quality and efficacy. Not compromising on safety and efficacy through the regulatory process is key to supporting a successful COVID-19 Immunisation Programme. Appendix Four has more detail on the Medsafe process. Following regulatory approval, officials will immediately provide Joint Ministers with recommendations on how to best use the Pfizer vaccine.

32 New Zealand regulatory decision on the Pfizer vaccine is anticipated in early February 2021. This timeline is strictly a best-case scenario. If all the necessary information and steps are met, a regulatory decision could be possible by Wednesday 3 February 2021 following the Medicines Assessment Committee meeting on Tuesday 2 February 2021.

[1] The EPA must approve the import and release of any vaccines that contain organisms new to New Zealand as defined by the Hazardous Substances and New Organisms Act 1996

33 Expected delivery schedules in New Zealand for the Pfizer vaccine have also been brought forward to mid-February 2021. However, like Australia, any delays in shipping or production could delay domestic roll-out. These delays are outside our control and at the discretion of the manufacturer.

34 Upon arrival of the Pfizer doses, there is a quality assurance step to ensure the vaccine is fit for purpose before the Ministry of Health takes ownership of the doses from Pfizer. This involves confirming receipt of delivery and that the vaccine has been kept at -70 degrees throughout the shipment, and that there have not been any breakages during transit. Officials anticipate that temperature checking the transponders with Pfizer will take half a day, and that unpacking, breaking down, and preparing the shipments. [will happen thereafter]

35 The table below outlines theses with anticipated timelines for the first four days following arrival in New Zealand of the first shipment of the Pfizer vaccine.

Day	Step	Temperature
1	Shipment of vaccine arrives in Auckland	-70 degrees
2-3	Quality Assurance process completed Shipment of vaccine is prepared and distributed	-70 degrees
3-4	Vaccination site receive vaccines and consumables Vaccination start	2-8 degrees

We have made progress on policies to support a successful COVID-19 Immunisation Programme

36 The COVID-19 Immunisation Programme is progressing at pace in order to be prepared to roll out COVID-19 vaccines as soon as they are approved and available for distribution in New Zealand (see Appendix Five for the COVID-19 Immunisation Programme blueprint). Led by the Ministry of Health, this work is focused on planning, managing, delivering, and monitoring the vaccine throughout New Zealand.

37 The Ministry continues to engage fortnightly with an external Immunisation Implementation Advisory Group (IIAG), which has strong Māori and Pacific representation [CAB-20-MIN-0509 refers].

38 It is important to note that this COVID-19 Immunisation Programme is focused on roll-out in New Zealand. Officials are working through impacts of COVID-19 immunisation for offshore New Zealanders, including public service staff serving offshore. We are also supporting the Pacific with access to the COVID-19 vaccine. The supporting Cabinet Paper *Provision of COVID-19 vaccines for the Polynesian countries* will have further details.

Our immunisation plan has evolved rapidly over the past month

39 The COVID-19 Immunisation Implementation plan consists of three phases from delivering the initial (constrained) supply, through scaling up and then full-scale delivery. The table below provides more detail on each phase. Phase 1a is initiated with Phase 1b following concurrently shortly after. Appointment management in the initial phase will be managed by employers and providers, with the potential to offer more technology enablement over time as the COVID-19 Immunisation Programme scales.

Phase		**Objective**	**Cohort Size**	**Focus[2]**	**Approach**
Initial Supply (constrained)	Phase 1a	Protect the border	12,600	Border, MIQF workers (Tier 1a)	Delivery through workplaces
	Phase 1b	Protect high risk workers and border workers household contacts	212,625	Rest of Tier 1 and Tier 2	Delivery through workplaces and community pop ups
Scaling Up	Phase 2	Ramp up	1,500,000	Tier 3	Delivery through workplaces and community pop ups
Full Scale Delivery	Phase 3	Open access	3,900,000	General population	Delivery through workplaces, community pop ups, GP Facilities, Pharmacies, and DHB Facilities.

40 An implementation plan has been developed for Phase 1 of the COVID-19 Immunisation Programme to ensure the vaccine can be delivered to the right people at the right time. Additional detail on what will be delivered during Phase 1 is outlined below at paras 42 to 46.

41 The plan is underpinned by a number of assumptions that speak to the large number of variables, including broader contextual factors, sequencing scenarios, and manufacturers delivery schedules. The implementation plan will change and evolve

[2] Under low/no transmission scenario,Tier 1 includes Border/MIQF workforces and their household contacts, Tier two includes high risk workforces, and people at highest risk of transmission and severe health outcomes in the community, and Tier 3 includes people at risk of serious illness and the workforces supporting then. See Appendix One for further detail.

should the assumptions change, including responding to a change in alert levels, for example. Key planning assumptions and limitations for Phase 1 include:

41.1. the influenza campaign will progress in 2021 as planned, and individuals will not receive an influenza and COVID-19 vaccination at the same time, although further clinical evidence has been urgently sought;

41.2. New Zealand is likely to remain in alert level 1, which allows for large-scale immunisation without restrictions on gatherings, social distancing, or other public health controls. If alert levels change, Phase 1 implementation delivery models will to change in order to respond to the context;

41.3. we will be implementing Scenario One, Tier 1 and 2 of the Sequencing Framework and focus on immunising the border, MIQ workforces, and their household contacts, high risk health workforce such as aged residential care workers, residents in aged residential care, and high-risk frontline public sector and emergency services; and

41.4. arrival of Pfizer's vaccine in New Zealand in alignment with delivery schedules. The plan will need to adapt to any changes in the manufacturers' delivery schedules.

42 As New Zealand's context changes and if planning assumptions are impacted, advice will be provided to Ministers on the implications for Phase 1 implementation and how we will adjust the plan to manage the change.

Phase 1 – Initial Supply Implementation Plan

43 Phase 1 implementation focuses on service delivery through workplaces, outreach services and community pop-up sites.

44 Distribution and logistical arrangements have been made to ensure a vaccine can be used once delivered onshore. This includes:

44.1. Inventory management – officials are engaging with DHBs about how inventory management processes integrate with their existing systems. The inventory management process design will enable us to track and trace the vaccine at any point in time to assist with managing supply and demand.

44.2. Storage infrastructure and consumables – at a national level, we have the capacity to store and receive all vaccines should they arrive at once. Ultra-low temperature freezers (-70 degrees) and cold chain capability for the Pfizer vaccine has arrived onshore and will be operational in Auckland and Christchurch by mid-February. In response to global demand and long lead times, the Ministry of Health has proactively purchased the majority of consumables to administer the vaccine, which are expected to arrive in January and February. This includes items such as specific needles, syringes, saline, waste, sundry and shipping consumables.

44.3. Transport solutions – are being designed and commissioned with a number of providers engaged to deliver a robust on demand network with cold-chain

capability. This includes close temperature monitoring to ensure temperature remains within the specified limits and wastage is avoided. Officials are developing processes with Road Transport and Police to ensure efficient air and road transport of the vaccines.

45 We have proactively engaged the health workforce and are working closely with the Immunisation Advisory Centre (IMAC) to provide training on COVID-19 vaccines, to start in February 2021.

45.1. the training schedule is driven by the receipt of information from vaccine manufacturers, developing it into material for a New Zealand context to ensure it enables capable and culturally safe vaccinators, receiving clinical advice on any matters not covered by this information.

45.2. existing vaccinators, around 400 – 500 FTE, will be predominantly used for the initial roll out and they will only need to complete a short online COVID-19 vaccine module for the Pfizer vaccine. Over time, this workforce will be supported by an additional 2,000 – 3,000 FTE vaccinators comprising of non-practicing health professionals who will be trained in COVID-19 vaccine delivery. The workforce will continue to be scaled as we receive the vaccine in New Zealand.

46 The COVID-19 Immunisation Register (CIR) (formerly known as the National Immunisation Solution) is the technology solution that is being developed to support the roll-out of COVID-19 vaccines. Significant progress has been made on the CIR and it will be ready to use should the vaccine arrive at any stage, with further iterations of the CIR to be rolled out over 2021.

47 Methods of service delivery are being worked through between DHBs and the Ministry of Health. We are working closely with DHBs to develop a nationally consistent model that can tailor services to different communities to ensure local need is met, in line with national objectives.

47.1. where possible, methods of service delivery will leverage the existing capability and capacity of the health system, noting that new approaches to service delivery will be required.

47.2. for most individuals (and people they live with) identified in Tier 1 of the Sequencing Framework, immunisation will be provided in their workplaces in line with existing COVID-19 testing schedules, or in a community pop-up for household members. Delivery partners for these groups are currently collecting data to support roll-out.

47.3. throughout this initial phase, service delivery models will be tested, challenges addressed, and plans refined to manage scaling up in subsequent phases.

We are committed to achieving equitable outcomes for Māori, Pacific peoples and population groups at particular risk from COVID-19

48 To achieve equitable outcomes, officials are focused on removing barriers and promoting accessibility. Officials are building on the lessons learned from the

influenza campaign in 2020 to ensure specific COVID-19 immunisation delivery strategies for Māori and Pacific are adopted. To date the following activities have been prioritised:

48.1. investing an estimated $20.25 million to support Māori and Pacific service delivery options to make it easy for people to access the vaccine;

48.2. building Hauora Māori and Pacific provider feedback into the design of the COVID-19 Immunisation Programme;

48.3. liaising with DHBs to capitalise on existing relationships with Māori and Pacific health providers and iwi relationships, to ensure service delivery meets the needs of local Māori and Pacific people;

48.4. IMAC have been commissioned to ensure the cultural competencies of the vaccinator workforce, and are:

48.4.1. working with Māori and Pacific partner organisations to develop training and support material;

48.4.2. delivering training courses specifically for Māori and Pacific vaccinators; and

48.4.3. employing Māori and Pacific Peoples as engagement advisors.

48.5. tailoring the COVID-19 Immunisation Campaign for Māori and Pacific audiences to promote uptake. The Ministry of Health has directly commissioned a Māori communications provider to develop tailored national content for Māori and to embed Māori and Pacific expertise within the communication and engagement approach.

48.6. investing in a range of implementation options for Māori and Pacific peoples, for example, Marae and Church based delivery.

49 The Ministry is actively reinforcing its engagement with Iwi and representative bodies across the COVID-19 Immunisation Programme.

Phases 2 and 3 – Plan for delivering the vaccine to wider New Zealand

50 While planning is largely focused on the near-term delivery, officials are preparing for a robust COVID-19 Immunisation Programme delivery in the longer term which includes Phases 2 and 3, recognising that the scale and complexity of the COVID-19 Immunisation Programme will increase over time. As the COVID-19 Immunisation Programme scales up and continues to build as more vaccines arrive in New Zealand, officials will continue to refine the COVID-19 Immunisation Programme.

51 A key component of the COVID-19 Immunisation Programme is post immunisation monitoring. This includes monitoring safety and efficacy (including adverse events), with reporting on uptake and providing mechanisms that will enable us to adapt our approach if needed.

52 Cabinet previously requested a report-back on issues around General Practitioner (GP) vaccinator fees and co-payments for COVID-19 immunisation, in relation to its announcements that people will be able to access COVID-19 vaccines for free.

s 9(2)(g)(i), s 9(2)(j)

[redacted]

We are seeking your decision on key issues to support a successful COVID-19 Immunisation Programme

53 There are a number of decisions sought in this section on the Decision to Use and Sequencing Frameworks, as well as decisions on eligibility. This section also provides an update on vaccine purchasing, and COVID-19 Immunisation Programme readiness.

We are seeking your endorsement of the proposed Decision to Use Framework

54 The COVID-19 Elimination Strategy, along with the Vaccine Purchasing strategy provides New Zealand with an opportunity to make choices about how, when and which vaccines to use. This means there are opportunities to consider vaccine candidates against the wider portfolio and to determine which vaccine(s) would best support the COVID-19 Immunisation Programme objectives.

55 The Decision to Use Framework outlined below and in Appendix Five provides a robust process for decisions on how to use COVID-19 vaccines, who to use them for and when to use them.

56 We are expecting to purchase and take delivery of up to 14.91 million courses of different COVID-19 vaccines over time. At this stage of vaccine development and availability of information, we expect the four vaccines (Pfizer/BioNTech, Janssen, AstraZeneca and Novavax) will vary in their suitability for different populations, safety, efficacy, price, number of doses, and in their storage, and distribution requirements.

57 These volumes mean that we should have the opportunity to choose which vaccines to use or deploy and how we use them to best support a successful COVID-19 Immunisation Programme.

Objectives for the Decision to Use Framework

58 As we get closer to a Medsafe regulatory decision on vaccine or vaccines, there will be more information about vaccine characteristics (such as safety and efficacy information) that will support decision making on vaccine use and how to best support a successful COVID-19 Immunisation Programme

59 There will still be uncertainty and information gaps about the vaccine(s). To help guide decision-making, decisions on any vaccine will be based on the wider COVID-19 Immunisation Strategy principles, and considered against our overall responsibility to uphold Te Tiriti o Waitangi.

When do we need to make a decision?

60 Officials have advised that there is likely to be a sequence of decisions or decision windows for each vaccine when or if approved for use by Medsafe in New Zealand.

61 These decision windows allow us to understand where it is feasible to consider multiple vaccines in our portfolio for deployment, which ones would best support the COVID-19 Immunisation Programme and the broad timeframes for vaccination if a Decision to Use is made.

62 The decision window will follow regulatory approval and a decision needs to be made for each vaccine candidate. Due to the close indicative delivery schedules, and the timing of regulation, the Decision to Use will need to consider more than one vaccine in the portfolio against each other.

We are supporting the Pacific with access to a COVID-19 Vaccine

63 A key objective of the COVID-19 Vaccine Strategy is ensuring access to safe and effective vaccines for the Pacific nations, with a particular focus on Sāmoa, Tonga, Tuvalu, and the Realm countries the Cook Islands, Niue and Tokelau. As part of our portfolio approach we have been purchasing vaccines for New Zealand and Polynesia [CAB-20-MIN-0229.01 refers].

64 s 9(2)(f)(iv) [redacted]

65 For the wider Pacific, we are working with key partners such as Australia, the United States, France, the European Union and Japan as well as the World Health Organization, United Nations Children's Fund, World Bank, and Asian Development Bank to support global equitable access. 6(b)(ii) [redacted]

While vaccine supplies are limited allocation will be guided by the Sequencing Framework

66 Cabinet agreed in principle to a Sequencing Framework to guide use of the vaccine where supply is limited [CAB-20-MIN-0509 refers]. Cabinet previously agreed in that the Sequencing Framework would be underpinned by the principles of Te Tiriti o Waitangi, equity, wellbeing, and legacy. The Sequencing Framework considers the relative risks faced by people in three broad scenarios where: (1) New Zealand is in low or no community transmission, (2) is facing controlled outbreaks, or (3) there is widespread transmission. Under a low or no community transmission scenario, the

first groups in line for vaccination (Tier 1) include workers closest to the border, and their household contacts.

67 Since December 2020, the Sequencing Framework has been updated to reflect the latest evidence and is attached at Appendix One. The objectives of the Sequencing Framework have been updated to reflect uncertainty around the ability for the vaccine to prevent transmission compared to protecting individuals against the disease.

Epidemiological Scenario	**First objective**
Scenario 1: Low/no transmission	To protect those with the highest risk of exposure to COVID-19 and potentially prevent transmission
Scenario 2: Controlled outbreaks	To protect people at the higher risk of infection, at outbreak localities and to potentially reduce transmission
Scenario 3: Widespread transmission	To protect those who are most at risk of serious health outcomes and to potentially reduce transmission

68 A review of scientific evidence has quantified the risk of serious illness and mortality for certain populations. This has highlighted the need for us to work to protect these groups as quickly as possible while responding to the very high risk of exposure certain workforces face at the border or in the community.

69 We are confident the sequencing under this scenario effectively manages the risks to our most at risk of population groups, and will also support equitable outcomes and protect all New Zealanders as we continue to pursue the COVID-19 Elimination Strategy. This means that if the first vaccine available for distribution is Pfizer, the Ministry would be able to distribute the 225,000 courses in line with Tiers 1 and 2 of the Sequencing Framework.

The Ministry will continue to assess emerging evidence on sequencing and update the Sequencing Framework in accordance

70 As the Ministry prepares for implementation, officials will continue to assess the emerging evidence on risks associated with COVID-19. To guide this, officials will monitor for particular risks faced by certain populations and effectiveness of vaccines in reducing transmission from technical and scientific experts.

71 In particular, it is important to note that there is some local evidence about groups at higher risk of serious illness, including Māori and Pacific peoples. Officials will review this evidence alongside operational considerations to determine the best approach, particularly for Tier 3, to meet obligations under Te Tiriti o Waitangi, and to promote equitable outcomes.

72 We propose that Cabinet delegate oversight and any policy decision-making on the sequencing framework to Joint Ministers. This is to ensure the COVID-19 Immunisation Programme can pivot quickly should the situation or evidence change.

73 The Ministry of Health will continue to provide operational guidance on who is included within the scope of the current proposed Tiers of the Sequencing Framework and this will be delegated to the Director-General of Health.

The Sequencing Framework will be implemented when supplies are limited

74 Officials will be pragmatic about how to operationalise the Sequencing Framework. Each scenario identifies at-risk population cohorts in three tiers. Tier 1 will be offered the vaccine first, followed by Tier 2 and then Tier 3, with a pragmatic approach to delivery. This means, for example, if we have enough vaccine supply to vaccinate Tiers 1 and 2 at the same time, we will do so.

75 Officials are working though how to best transition through the tiers, noting that in practice there will likely be parallel implementation of tiers at times where volumes allow. This includes working to identify when a likely "national roll-out" can commence, if the Government is in a position to offer the vaccine to everyone in New Zealand (if supplies were no longer limited). Based on expected delivery schedules, and the estimated sizes of the key target populations in the tiers, officials estimate that this is likely to occur in quarter three of 2021. However, this depends on:

75.1. decisions about the use of the vaccines;

75.2. volume and timing of vaccine delivery; and

75.3. rates of uptake.

76 The service design for this national roll-out will have a strong focus on equity. This means that while we may move towards encouraging everyone in New Zealand to be immunised, there will continue to be an emphasis on targeting additional vaccinator resources to those most at risk or those who require assistance to access vaccines

77 We seek in principle agreement to the updated Sequencing Framework, noting that the Ministry of Health is preparing for implementation on the basis of the low/no transmission scenario (Scenario One).

To maximise uptake of the COVID-19 vaccine we recommend that publicly funded COVID-19 immunisation is made available to everyone in New Zealand

78 To work towards population immunity and uphold the principles of the COVID-19 Immunisation Strategy, it is important to maximise uptake of the COVID-19 vaccine. To support this, the Government has previously announced that immunisation will be offered free of charge. We seek Cabinet agreement to confirm who will be eligible for free COVID-19 immunisation and note the financial implications of this.

Without policy change most non-residents would not be eligible for free COVID-19 immunisation

79 Eligibility for most publicly funded immunisations is determined by the Eligibility Direction. If this were applied to the COVID-19 vaccine, most non-residents would not be eligible for free vaccination under the Health and Disability Services Eligibility Direction 2011. The table below estimates how many people this could include.

Immigration status	**Approximate number of people in New Zealand (as at January 2021)**
Visa holders with the right to work (including Recognised Seasonal Employer workers)	187,000 (NB: some may already be eligible if they intend to be in New Zealand for two years or more)
Students	40,000 (NB: some may already be eligible if they are under 18 years or claiming refugee or protection status)[3]
Visitors	30,000 (NB: some may already be eligible if they are under 18 years)
No visa (ie. in New Zealand unlawfully)	~13,000 (approximately)
Australian citizens or permanent residents who intend to reside in New Zealand for less than two years.	Unknown
Approximate total	**270,000**

80 Some of those not currently eligible may be particularly at risks of contracting and transmitting COVID-19 or could be included in Tiers 1 or 2 of the Sequencing Framework, depending on where they work.

81 This proposal would also provide access for diplomatic and consular staff from other countries in New Zealand, 6(a), s 9(2)(j) [redacted]

[3] Under 18 year olds and refugees are already eligible for publicly funded immunisation under the existing Eligibility Direction 2011.

We propose expanding eligibility to free COVID-19 immunisation anyone in New Zealand

82 We need to encourage uptake of COVID-19 vaccines to achieve the short-term objectives of the Sequencing Framework and to work towards population immunity. This requires us to make COVID-19 immunisation free and easy to access for everyone and anyone.

83 To support this, subject to Cabinet's decision, the Minister of Health intends to issue a Ministerial Direction under section 32 of the New Zealand Public Health and Disability Act 2000 to expand eligibility for publicly funded COVID-19 immunisation to everyone in New Zealand regardless of immigration status. This process requires the Minister to consult with DHBs before issuing the direction. Ministry officials will consult with DHBs with urgency. The Minister of Health will subsequently consider DHB feedback before issuing the final direction.

84 If the consultation feedback suggests that significant change is needed to this policy position, we will report back to Cabinet with further advice.

85 We seek Cabinet's in principle agreement to the policy of expanding eligibility for publicly funded COVID-19 immunisation to everyone in New Zealand, regardless of immigration status. This would be consistent with the eligibility for COVID-19 testing and health care services for a person who has, or is suspected of having COVID-19. For example, anyone coming into New Zealand is already being issued with a National Health Index number to enable linking of test results to individuals. Access to COVID-19 immunisation for non-residents aligns with the Sequencing Framework.

86 The Ministry of Health will partner with other agencies, to promote access to the COVID-19 vaccine, including for those who are in New Zealand unlawfully that may otherwise be reluctant to interact with Government services.

87 Should this policy be confirmed, we would provide guidance for providers about eligibility and, as with COVID-19 testing, clear communications that immigration status would not be shared.

Under current border settings, the fiscal cost can be absorbed within existing funding

88 We expect that the cost of expanding access to all people in New Zealand can be absorbed within the existing appropriation at this time, as visitor numbers remain low. We do not have a robust estimate of the number of people who would take up COVID-19 immunisation that would not have otherwise if they remained ineligible. As an indication, it would cost approximately $16.7 million to immunise up to 270,000 people, the estimated number of people in New Zealand who may not otherwise be eligible for immunisation based on their immigration status. This cost estimate may change depending on how long this policy is in place.

89 Any future policy work to change border controls would need to consider the impact on COVID-19 immunisation, given that relaxing the borders would increase the number of people on temporary visas.

90 s 9(2)(g)(i), s 9(2)(f)(iv) [redacted]

91 Work is underway internationally (including through the OECD, and World Health Organisation) to consider how states can work together to safely open borders. This includes consideration of safely sharing information about verified vaccination status of intending travellers between countries.

Financial Implications

92 The financial implications arising directly from the proposals in this paper will be met within the existing appropriation of Implementing the COVID-19 Vaccine Strategy Multi Category Appropriation until December 2021.

93 s 9(2)(j) [redacted]

Population Implications

94 Access to COVID-19 vaccines will be given to all New Zealanders over time. While supply of the vaccine is constrained we will utilise the Sequencing Framework set out at Appendix One to guide decision making in relation to rollout.

95 The Sequencing Framework takes into consideration the scenario New Zealand is in, along with the characteristics of the population. Broadly this means that the populations that have access to the vaccine will initially be to protect the border, then critical workforces, then those most at risk. Once supply is not constrained, access will be opened to the whole population of New Zealand. As such, the initial focus will be on the personal protection of individuals that will develop into protection of the New Zealand population.

96 Officials are continuing to review evidence in relation to the vaccines and the virus to ensure that equitable access to the vaccine is supported throughout the COVID-19 Immunisation Programme with a focus on those most at risk.

Human Rights

97 As previously advised, vaccines may be made available earlier to certain people or populations when supplies are limited as per the Sequencing Framework. As with any limited health resource, there will be a need to prioritise access for a time. However, it

is important to note that we have purchased enough vaccines for every person in New Zealand. All people are equally deserving of care, but certain risk characteristics and limited supply will justify prioritisation of vaccine delivery.

98 Vaccines may be made available earlier to certain persons or groups of persons if supplies are limited. This means individuals may be eligible to receive a COVID-19 vaccine sooner who may also have a disability or health condition, be a certain age, sex, ethnicity, or family status. If this differential treatment occurs it will be based on particular risk faced by these people, as well as promoting equitable outcomes.

99 This raises possible issues around discrimination under section 19 of the New Zealand Bill of Rights Act 1993 and section 21 of the Human Rights Act 1993 by potentially prioritising access to specified groups. This response is proportionate and based on evidence and decision-making frameworks underpinned by the principle of equity, with any discrimination in favour of people at greater risk. As such, it is demonstrably justified in a free and democratic society in accordance with section 5 of the Bill of Rights Act.

Consultation

100 The Ministry of Health has consulted with the Ministries of Foreign Affairs and Trade, Pacific Peoples, Business, Innovation and Employment, and Justice. The Treasury, Te Arawhiti, Te Puni Kōkiri and the Department of Corrections, PHARMAC and Police have also been consulted. The Department of the Prime Minister and Cabinet has been informed.

101 The Ministry of Health will continue to work with other agencies on delivering the COVID-19 Immunisation Programme. It is working with Te Arawhiti and Te Puni Kōkiri on the most appropriate forum to engage with iwi and how it can apply the Te Arawhiti Engagement Framework and Guidelines. The Ministry will also work closely with the Ministry for Pacific Peoples on engagement and delivery.

Communications

102 The COVID-19 Immunisation Programme communications campaign is underway and will ramp up over 2021.

103 The overarching purpose of the public communications strategy is to build trust and confidence in the COVID-19 Immunisation Programme, which in turn will encourage uptake.

104 Campaign planning has identified three main phases of work over the next 18 months:

104.1. Phase 1 (Quarter 1, 2021) – focuses on ensuring people have the correct information about the safety and efficacy of the vaccine. The aim is to address key questions and concerns people may have about COVID-19 vaccines, clarifying New Zealand's context compared to other countries, and sharing information about vaccine timing and sequencing.

104.2. Phase 2 (Quarter 2 – Quarter 4 2021) – the aim is to encourage uptake, support access to vaccines and address any remaining questions. A service design

element is also important here as the campaign would look to support outreach.

104.3. Phase 3 (2022 onwards) – the third phase would continue to encourage uptake in the event the campaign continues into 2022.

105 At this stage officials have planned for five to six different campaign streams that can tailor messaging to certain population cohorts. Each stream will have a dedicated campaign partner and resources to support roll out. The campaign streams include:

105.1. **Nationwide** – working with a mainstream provider, such as during the Level 4 lockdown, to support the broad-based public information for all audiences;

105.2. **Māori** – working with Māori providers, iwi and communities to support Māori uptake and engagement;

105.3. **Pacific peoples** – working with Pacific providers, networks and leaders to support engagement and uptake for Pacific peoples;

105.4. **Migrant communities** – engaging migrant communities through Department of Internal Affairs, who also provide translation services; and

105.5. **Health workforce** – a dedicated stream of activity with its own resources to support the needs of our health workforce.

106 As we begin to frame up the campaign approaches, we are seeing advice from disability networks (via DPMC) to help ensure our campaign approach incorporates accessible content and accessible formats.

We are using research and sentiment monitoring to inform our approach, while leveraging the successful and identifiable Unite against COVID-19 campaign

107 A critical component for the success of any public information campaign is to track public sentiment, which will be particularly important in the New Zealand context. Research has been commissioned and officials are already using this information to inform campaign planning and Ministry responses to key questions and concerns raised by the public. Officials are also working closely with key spokespeople to ensure that messaging resonates with the public.

108 Both the Ministry of Health and All of Government Group (AOG) will monitor key channels to identify any trending topics, challenges, questions, or areas of interest that require a response. Engagement with a range of stakeholders is ongoing and will continue throughout 2021.

109 A stakeholder network has been established and key contacts receive regular updates about the COVID-19 Immunisation Programme. We are working closely with DHBs to collaborate on a number of aspects of the COVID-19 Immunisation Programme, including service design and workforce development.

110 The Ministry is engaging with Māori and Pacific stakeholders to co-design targeted communications approaches and is working with other agencies to ensure that messaging is appropriate for other migrant communities.

111 6(b)(i) [redacted]

Proactive Release

112 We intend to proactively release this Cabinet paper within 30 working days, with redactions as appropriate under the Official Information Act 1982.

Recommendations

The Minister for COVID-19 Response, Minister of Health and the Associate Minister of Health recommend that Cabinet:

1 note that Cabinet previously agreed that the purpose of the COVID-19 Immunisation Strategy is to support the "best use" of COVID-19 vaccines, while upholding and honouring Te Tiriti o Waitangi obligations and promoting equity;

2 agree that Joint Ministers (Prime Minister, Minister of Finance, Minster for COVID-19 Response, Minister of Health, Associate Minister of Health, Minister of Research, Science and Innovation and the Minister of Foreign Affairs) have the power to act in order to ensure timely decision making on the COVID-19 Immunisation Programme;

Vaccine purchasing

3 note we have entered into four Advance Purchase Arrangements with vaccine manufactures, totalling 14.91 million courses;

4 note that Medsafe is prioritising the evaluation of COVID-19 vaccines to obtain an approved vaccine more quickly without compromising the integrity of the process or on the safety, quality, and efficacy of the vaccines;

COVID-19 Immunisation Programme

5 note the Ministry is on track to begin Immunisation in late February 2021, should a vaccine be available and approved for use;

6 note that immunisation activity is expected to ramp up over the course of 2021 as system capacity and vaccine volumes increase;

Decision to Use Framework

7 note that officials have developed a proposed Decision to Use Framework to provide a robust process for decisions on how to use COVID-19 vaccines, who to use them for and when to use them;

8 endorse the proposed Decision to Use Framework that is intended clarify in what context and when a decision needs to be made, informed by current science and clinical information and an understanding of the risks and benefits;

9 agree that officials will seek Joint Ministers' Decision to Use once the first vaccine gains regulatory approval so a decision on vaccine use can be made;

10 note that officials will continue to refine the Decision to Use Framework and process, including consulting with key stakeholders;

Sequencing Framework

11 note that Cabinet previously agreed in principle to the Sequencing Framework, noting that officials would continue to review it based on emerging evidence;

12 note that the objectives of the Sequencing Framework have been updated to reflect uncertainty around the ability of the vaccine to prevent transmission compared to protecting individuals against the disease;

13 agree in principle to the updated Sequencing Framework as outlined in Appendix One, noting this is based on the latest available evidence and analysis of the risks from COVID-19 to New Zealand;

14 agree that oversight and any policy decision-making on the Sequencing Framework will be delegated to the Joint Ministers as identified at Recommendation 2;

15 note the Ministry of Health is preparing for implementation on the basis of low/no transmission scenario which is New Zealand's current situation;

16 note that the Director-General of Health has the discretion to approve operational guidance on who is included within the scope of the current proposed tiers of the Sequencing Framework;

Eligibility for publicly funded COVID-19 immunisation

17 note that most people on temporary visas, Australians in New Zealand for less than two years, and people who are in New Zealand unlawfully, are not generally eligible for publicly funded health and disability services such as immunisation;

18 note that enabling everyone in New Zealand access to publicly funded COVID-19 immunisation, regardless of residency status, supports the elimination strategy and our goal of achieving population immunity over time;

19 agree in principle to expand eligibility to publicly funded COVID-19 immunisation to everyone in New Zealand regardless of immigration status;

20 note that to enable this, the Minister of Health will establish a Ministerial Direction under section 32 of the Public Health and Disability Act, but this is subject to consultation with DHBs;

21 note that the Minister of Health will make the final decision on the Ministerial Direction, but will consult with Cabinet if any significant changes to the policy are required;

22 note that it is expected that the cost of expanding eligibility can be absorbed within existing funding while border settings remain unchanged;

Financial Implications

23 note that the financial implications arising directly from the proposals in this paper will be met within the existing appropriation of Implementing the COVID-19 Vaccine Strategy Multi Category Appropriation until December 2021.

Communications Strategy

24 note the overarching purpose of the public communications strategy is to build trust and confidence in the COVID-19 vaccines and the Immunisation Programme to encourage uptake;

25 note this will be achieved through a range of mechanisms including phased communications that build a narrative over time and using a range of communications providers that can tailor messaging to certain population cohorts to ensure the messages resonate.

Authorised for lodgement

Hon Chris Hipkins
Minister for COVID-19 Response

Hon Andrew Little
Minister of Health

Hon Dr Ayesha Verrall
Associate Minister of Health

Appendix One: High level summary of Sequencing Framework

COVID-19 Vaccine Sequencing Framework as at 29 January 2021

The purpose of the overarching COVID-19 Immunisation Strategy is to support "best use" of the vaccines while upholding Te Tiriti o Waitangi and promoting equity.

Part A: Sequencing Framework - Context and Approach

The purpose of the Sequencing Framework is:
To ensure the right people are vaccinated at the right time with the right vaccine and that the principles of Te Tiriti o Waitangi are upheld.

The Sequencing Framework is built on foundational principles linked to the COVID-19 Elimination and Immunisation Strategies

Overarching principles		COVID-19 Immunisation Strategy principles	Implications for Sequencing
Uphold and honour Te Tiriti o Waitangi	Equity	Equity	Promote equitable outcomes particularly for Māori, Pacific peoples and disabled people.
		Equal concern	Over time all eligible people will have access to the vaccine.
	Wellbeing	Minimise the health, social, economic, cultural harm of COVID-19	Reduce infection, transmission, morbidity, mortality, and social, economic and cultural harms.
		Regional responsibility	Reduce harm to the Pacific; promote the Pacific's ability to recover.
	Legacy	Value	Cost effectiveness; support recovery.
		Legitimacy	Act in the best interests of New Zealanders, promote trust in immunisation.

The key assumptions and considerations underpinning the Sequencing Framework include:

- Vaccines may have different effectiveness, for different populations
- Vaccines will protect individuals from serious illness, and may prevent transmission
- The short-medium term focus will be on increasing individual protection, and the medium-long term focus will be on population protection
- Public health measures will continue until population immunity is established
- Improved treatment is unlikely in the short term
- Vaccines will be publicly funded, approved by Medsafe, and voluntary

We are planning for three epidemiological scenarios with aligned objectives → protection and potentially preventing transmission

- Low/no community transmission → *To protect those at highest risk of exposure to COVID-19 and potentially prevent transmission*
- Clusters/controlled outbreaks → *To protect people closely connected to an outbreak and potentially reduce transmission*
- Widespread community transmission → *To protect those most at risk of serious illness and potentially reduce transmission*

Communities with the highest need for the vaccine: we have identified four (overlapping) groups more at risk of…

- Infection (or contracting) COVID-19
- Transmission (or spreading) COVID-19
- Serious illness or death if they contract COVID-19
- Negative cultural, social and economic impacts from the pandemic
  Note Māori and Pacific people are likely to be over-represented

Change protocol

- Emerging guidance, advice, analysis, and evidence will be reviewed and appropriate changes made to strengthen the Framework. The Ministry will provide advice to Joint Ministers, programme advisors and the Governance Group where substantive changes are proposed.

Part B: Sequencing Framework – Methodology

Step 1: Determine the epidemiological scenario and the characteristics of available vaccine/s
Scenario 1: Low/no community transmission
Scenario 2: Clusters and controlled outbreaks
Scenario 3: Widespread community transmission

Step 2: Apply Use Decision to use Framework

Step 3: Apply Sequencing Framework

Scenario 1: Low/no community transmission
→ Protect people at highest risk of infection and potentially prevent transmission

Tier 1: Protect the Border/MIQ workforces (and household contacts) (est. 55k)

Tier 2: Protect the high risk workforces (e.g. first responders)

Protect people at highest risk of transmission and severe health outcomes in the community (e.g. ARC residents) (est. 170k)

Tier 3: Protect the people most at risk of serious illness the workforces supporting them
- Older people
- People with disabilities and underlying conditions

Scenario 2: Clusters/controlled outbreaks
→ Protect people at highest risk of infection, vulnerable people in the community of the outbreak and potentially prevent transmission

Tier 1: Protect the Border/MIQ workforces (and household contacts) and at risk people in the region of outbreak

Tier 2: Protect the high risk workforces (e.g. f) near the region of outbreak

Tier 3: Protect the most vulnerable and the workforces supporting them
- Older people
- People with disabilities and underlying conditions
- People living in long-term residential care

Scenario 3: Widespread community transmission
→ Protect those most at risk of serious illness and potentially prevent transmission

Tier 1: Protect people with highest risk of serious illness
- Older people
- People with disabilities and underlying conditions
- People living in long-term residential care

Tier 2: Protect the high risk workforces (e.g. first responders) and other frontline health workers

Tier 3: All other population groups

Step 4: If there is insufficient vaccine for an entire cohort, allocate vaccines according to risk

Step 5: Population coverage monitoring (delivery against cohorts)

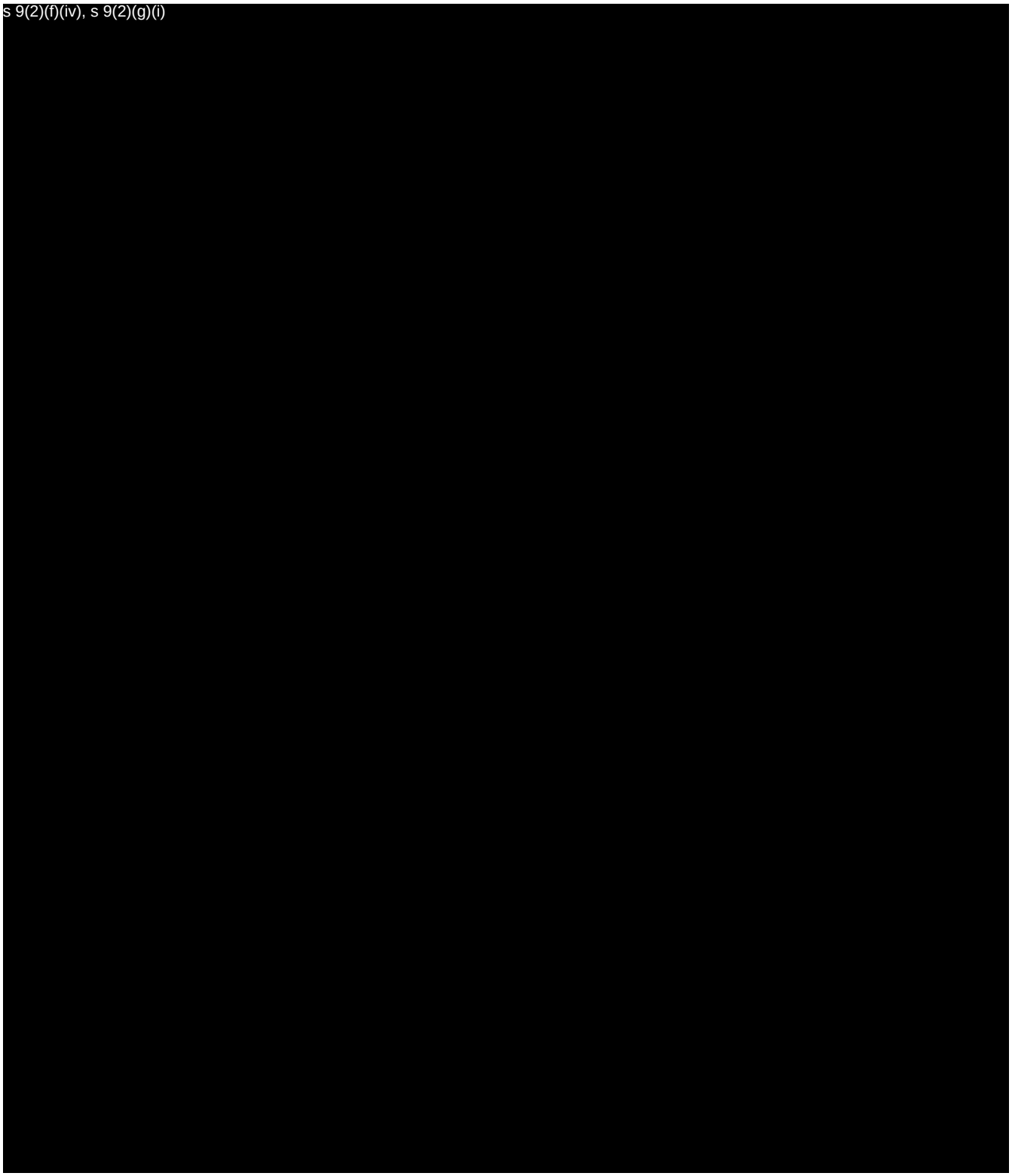
Appendix Two: Information on vaccine candidates as of 20 Jan 2021

Vaccine candidate	Stage of clinical trials[4]	Efficacy and safety results[5]	Global Regulatory Approvals	Handling requirements	Contraindications (exclusion criteria in trials)
Pfizer /BioNTech	• Phase I/II started in April 2020; results published in December 2020. • Phase II/III started in July 2020; interim results published in November 2020.	• Phase III trials indicate that the vaccine could as high as 95% effective at preventing symptomatic COVID-19 infection. • Vaccine was generally well tolerated across all populations.	Temporarily approved in more than 40 countries worldwide, including: • EUA[6] in the UK, Bahrain, US, Mexico, Kuwait, Iraq, Tunisia and Philippines • Interim approval in Canada • Conditional marketing authorization (CMA) in the EU • Emergency use listing by WHO	• Shipping: transported using ultra low temperature-cold chain (ULT) storage at -70 °C. • Storage: shelf life of 6 months in a ULT storage. • Handling: use within 5 days at 2-8 °C after removal from ULT storage.	• Groups excluded from trials: pregnancy, immunocompromised individuals, COVID-19 diagnosis, receipt of another COVID-19 vaccine, significant disease[7]. • Safety and immunogenicity data for adolescents (12-15) will be collected in the months ahead.
AstraZeneca	• Phase I/II/III trials are being conducted in various countries. • Interim analysis from Phase II/III announced November 2020.	• Initial data suggests overall 70.4% effective when pooling the data from the two dosing regimens used in trials. • Vaccine was generally well tolerated across all populations	• EUA in the UK, India, Argentina, Dominican Republic, El Salvador, Mexico and Morocco.	• Transported, stored and handled in normal cold chain conditions (2-8 °C). Stable for at least 6 months.	• Groups excluded from trials: those younger than 18, pregnancy, COVID-19 diagnosis, receipt of another COVID-19 vaccine, immunosuppressed state, significant disease.
Janssen	• Phase III trials have started in various countries. • Interim results from Phase I/II trial in Belgium announced in September 2020. • Interim results from Phase III expected at the end of January 2021.	• Recent phase II data indicates neutralizing antibodies in 90% of people after a single dose. • More data needed before drawing conclusions on the safety and efficacy of the vaccine.	• None yet. Anticipated the vaccine could be available for emergency use in early 2021.	• Shipping: transported frozen at -20 °C. • Storage: stored frozen until distributed. Shelf life up to 2 years at -20 °C. • Handling: stable for at least 3 months at 2-8 °C.	• Groups excluded from trials: those younger than 18 years, clinically significant acute illness, receipt of another COVID-19 vaccine, pregnancy.
Novavax	• Phase I/II/III trials are being conducted in various countries. • Interim results from Phase III expected March 2021.	• More data needed before drawing conclusions on the safety and efficacy of the vaccine.	• None yet.	• Shipping: in a ready-to-use liquid formulation that permits distribution using standard vaccine supply chain channels • Storage: stored at 2-8 °C.	• Groups excluded from trials: those younger than 18 years, COVID-19 diagnosis, receipt of another COVID-19 vaccine, unstable acute or chronic illness, cancer, and pregnancy.

[4] Phase I of clinical trials usually recruits dozens of participants and checks for safety; Phase II recruits hundreds of patients and tests safety and immunogenicity; and in Phase III trials, thousands of participants are recruited and the trials test for the safety and the efficacy are tested. For many COVID-19 vaccine trials, Phase I and II, and Phase II and III were combined to help speed up the development.
[5] Efficacy refers to the ability of the vaccine candidate preventing onset of COVID-19, and safety analyses typically considers any local reactions, systemic events, and any adverse events after vaccination.
[6] Emergency Use Authorisation (EUA) allows government to authorise the use of unapproved medical products. Some COVID-19 vaccines are being rolled out for EUA in several countries as full registration will take several years given the limited safety data at present.
[7] Additional studies are planned in pregnant women, children younger than 12 years, and those in special risk groups, such as the immunocompromised.

Appendix Three: Transition plan

s 9(2)(f)(iv), s 9(2)(g)(i)



Appendix Four: Medsafe approvals

Medsafe continues to accept rolling applications for efficient assessment of COVID-19 vaccines

1 Before decisions can be made about which vaccines to use and when, they need to be approved for use by Medsafe (under the Medicines Act 1981). This process is important to provide surety and transparency to help maintain public trust that medicines meet acceptable standards of safety, quality and efficacy. Not compromising on safety and efficacy through the regulatory process is key to supporting a successful COVID-19 Immunisation Programme.

2 The independent regulatory process undertaken by Medsafe objectively and impartially considers all information to weigh up the therapeutic value of the medicine against the risk of the use of the medicine. Currently Medsafe is accepting rolling submissions from companies to streamline its assessment processes. Medsafe is also prioritising the evaluation of COVID-19 vaccines to obtain an approved vaccine as fast as possible without compromising the integrity of the process.

3 Medsafe is working closely with its Australian counterpart, the Therapeutic Goods Administration (TGA) regarding the data both agencies are receiving from pharmaceutical companies about COVID-19 vaccines and any approval decisions made by Australia.

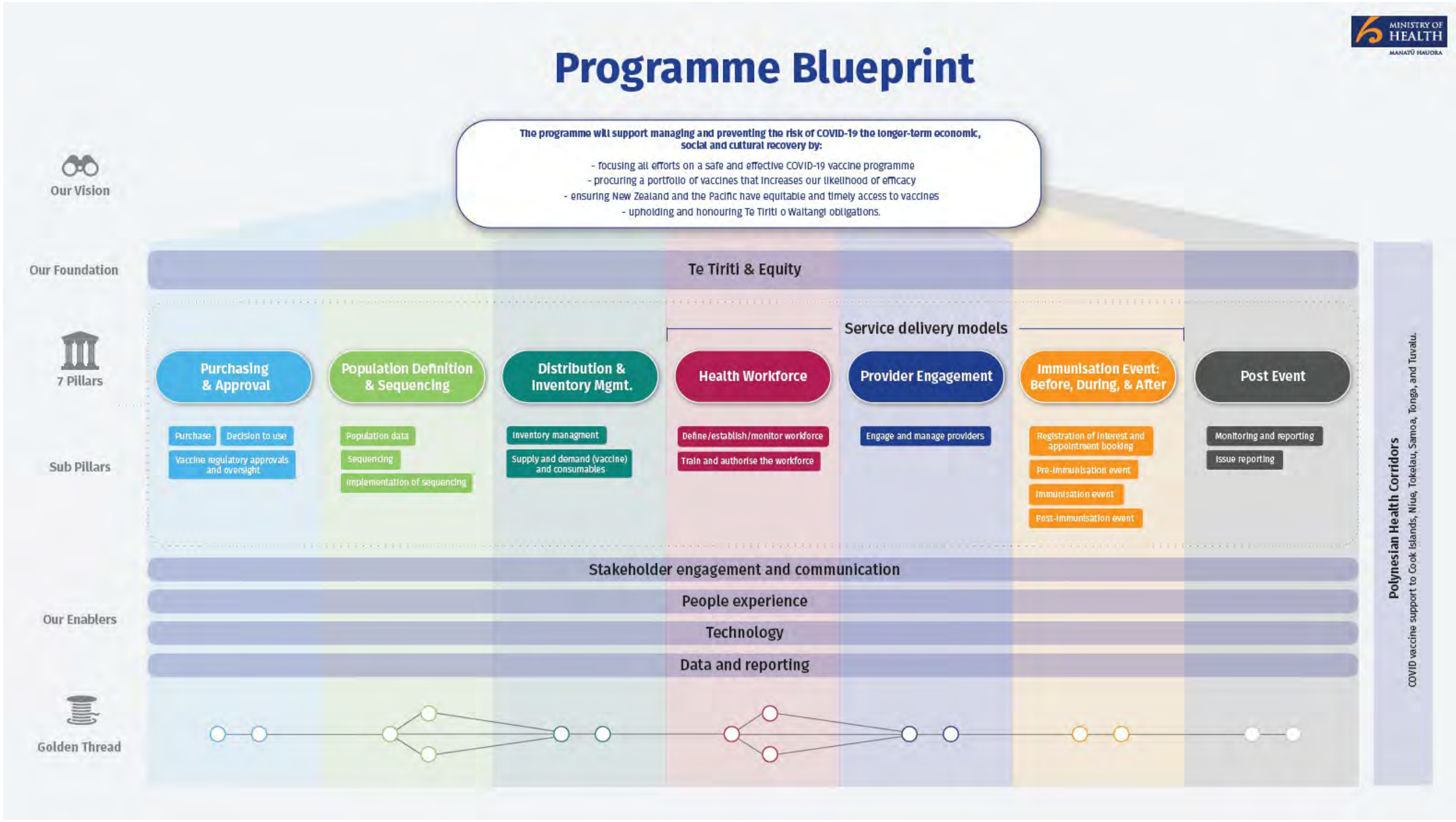
4 It is expected that initial Medsafe approval of any COVID-19 vaccine will be in the form of provisional consent, which can be granted under the Medicines Act 1981 if it is desirable that the medicine be sold, supplied, or used on a restricted basis for the treatment of a limited number of patients.

5 Medsafe has commissioned advice on the risks associated with the new COVID-19 variants identified around the world to support Medsafe's benefit risk assessment of vaccine candidates in New Zealand.

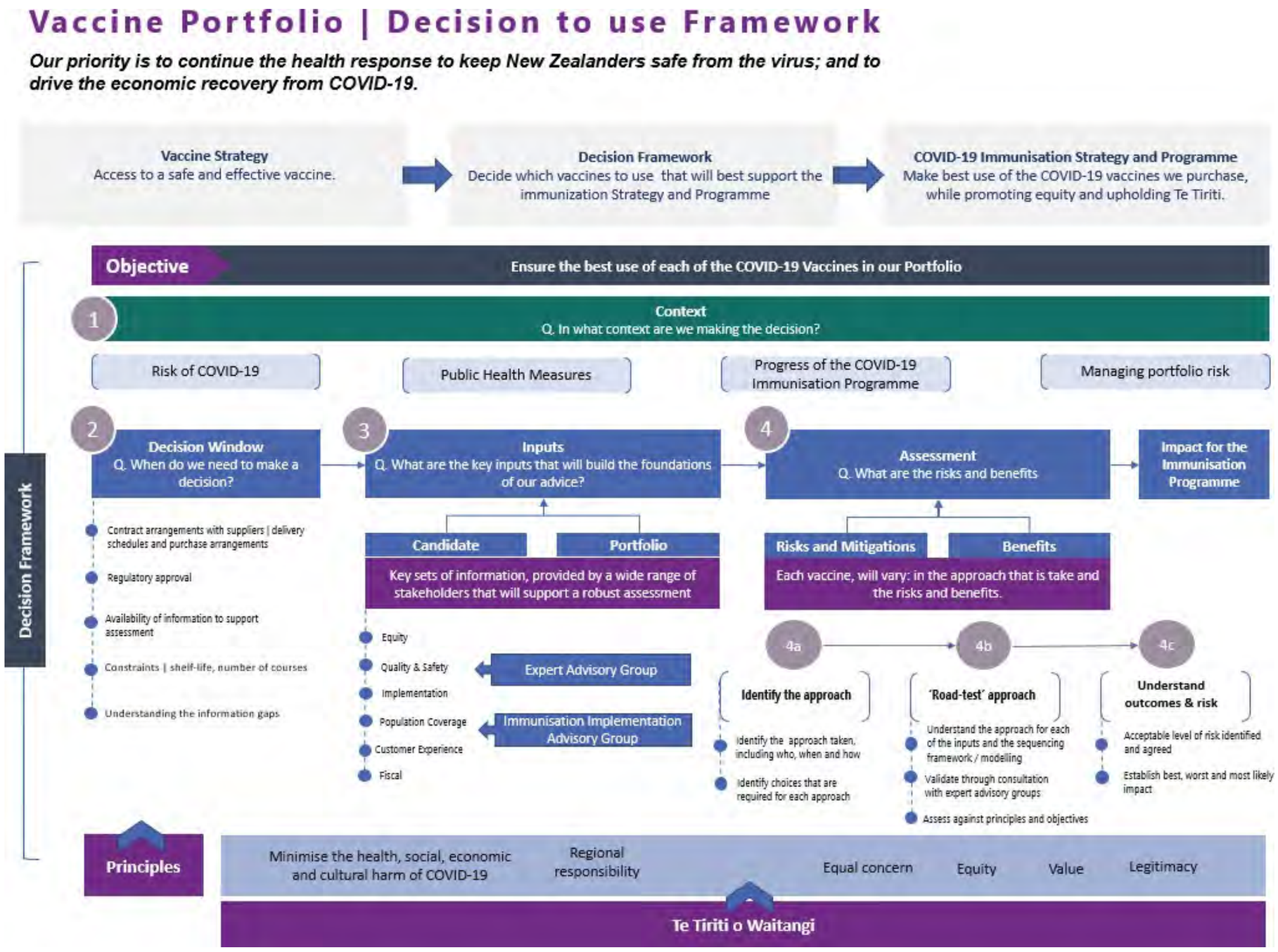
6 While Medsafe has already started to receive some information from Pfizer, Janssen, and AstraZeneca, manufacturers have only submitted limited data, and no vaccines have been provisionally approved by Medsafe so far.

7 Medsafe has provided an update on the possible timelines and process for assessment of the COVID-19 Pfizer vaccine. This timeline is strictly a best-case scenario. If all the necessary information and steps are met a regulatory decision could be possible by Wednesday 3 February 2021 following the Medicines Assessment Committee meeting on Tuesday 2 February 2021. Officials will keep you updated.

Appendix Five: COVID-19 Immunisation Programme Blueprint



Appendix Six: Proposed Framework for the Decision to Use COVID-19 Vaccines



CAB-21-MIN-0011

Cabinet

Minute of Decision

February 2021 Update on the COVID-19 Immunisation Strategy and Programme

Portfolio **COVID-19 Response**

On 2 February 2021, Cabinet:

1 **noted** that in December 2020, Cabinet agreed that the purpose of the COVID-19 Immunisation Strategy is to support the "best use" of COVID-19 vaccines, while upholding and honouring Te Tiriti o Waitangi obligations and promoting equity [CAB-20-MIN-0509];

2 **authorised** a group of Ministers comprising the Prime Minister, Minister of Finance, Minister for COVID-19 Response, Minister of Health, Associate Minister of Health (Hon Dr Ayesha Verrall), Minister of Research, Science and Innovation, and the Minister of Foreign Affairs (Joint Ministers) to have power to act in order to ensure timely decision making on the COVID-19 Immunisation Programme, where urgent decisions are required outside of the usual Cabinet meeting cycles;

Vaccine purchasing

3 **noted** that New Zealand has entered into four Advance Purchase Arrangements with vaccine manufactures, totalling 14.91 million courses;

4 **noted** that Medsafe is prioritising the evaluation of COVID-19 vaccines to obtain an approved vaccine more quickly without compromising the integrity of the process or on the safety, quality, and efficacy of the vaccines;

COVID-19 Immunisation Programme

5 **noted** that the Ministry of Health is on track to begin immunisation in late February 2021, should a vaccine be available and approved for use;

6 **noted** that immunisation activity is expected to ramp up over the course of 2021 as system capacity and vaccine volumes increase;

Decision to Use Framework

7 **noted** that officials have developed a proposed Decision to Use Framework to provide a robust process for decisions on how to use COVID-19 vaccines, who to use them for, and when to use them;

8 **endorsed** the proposed Decision to Use Framework set out in Appendix 6 of the submission attached to CAB-21-SUB-0011, that is intended to clarify in what context and when a decision needs to be made, informed by current science and clinical information and an understanding of the risks and benefits;

9 **agreed** that officials seek Cabinet or Joint Ministers' Decision to Use, depending on timing, once the first vaccine gains regulatory approval so a decision on vaccine use can be made;

10 **noted** that officials will continue to refine the Decision to Use Framework and process, including consulting with key stakeholders;

Sequencing Framework

11 **noted** that in December 2020, Cabinet agreed in principle to the Sequencing Framework, noting that officials would continue to review it based on emerging evidence [CAB-20-MIN-0509];

12 **noted** that the objectives of the Sequencing Framework have been updated to reflect uncertainty around the ability of the vaccine to prevent transmission compared to protecting individuals against the disease;

13 **agreed in principle** to the updated Sequencing Framework as outlined in Appendix One of the submission attached to CAB-21-SUB-0011, noting that this is based on the latest available evidence and analysis of the risks from COVID-19 to New Zealand;

14 **agreed** that oversight and any policy decision-making on the Sequencing Framework be delegated to Joint Ministers, where necessary for timing reasons;

15 **noted** that the Ministry of Health is preparing for implementation on the basis of a low/no transmission scenario, which is New Zealand's current situation;

16 **noted** that the Director-General of Health has the discretion to approve operational guidance on who is included within the scope of the current proposed tiers of the Sequencing Framework;

Eligibility for publicly funded COVID-19 immunisation

17 **noted** that most people on temporary visas, Australians in New Zealand for less than two years, and people who are in New Zealand unlawfully, are not generally eligible for publicly funded health and disability services such as immunisation;

18 **noted** that enabling everyone in New Zealand access to publicly funded COVID-19 immunisation, regardless of residency status, supports the elimination strategy and New Zealand's goal of achieving population immunity over time;

19 **agreed in principle** to expand eligibility to publicly funded COVID-19 immunisation to everyone in New Zealand regardless of immigration status, **subject to** consultation with District Health Boards;

20 **noted** that to enable this, the Minister of Health will establish a Ministerial Direction under section 32 of the New Zealand Public Health and Disability Act 2000, but that this is subject to consultation with District Health Boards;

21 **noted** that the Minister of Health will make the final decision on the Ministerial Direction, but will consult with Cabinet if any significant changes to the policy are required;

22 **noted** that it is expected that the cost of expanding eligibility can be absorbed within existing funding while border settings remain unchanged;

Financial implications

23 **noted** that the financial implications arising directly from the proposals in the paper under CAB-21-SUB-0011 will be met within the existing appropriation of Implementing the COVID-19 Vaccine Strategy Multi Category Appropriation until December 2021;

Communications strategy

24 **noted** that the overarching purpose of the public communications strategy is to build trust and confidence in the COVID-19 vaccines and the Immunisation Programme to encourage uptake;

25 **noted** that this will be achieved through a range of mechanisms including phased communications that build a narrative over time and using a range of communications providers that can tailor messaging to certain population cohorts to ensure the messages resonate.

Michael Webster
Secretary of the Cabinet

CAB-21-MIN-0350

Cabinet

Minute of Decision

COVID-19 Vaccine Strategy: Future Vaccine Portfolio

Portfolio **COVID-19 Response**

On 30 August 2021, Cabinet:

1 **noted** that the Vaccine Strategy has enabled New Zealand to achieve a number of key outcomes including:

1.1 securing a portfolio of vaccines to manage risks and ensure supply of a safe and effective vaccine;

1.2 enabling the rollout of the CVIP to offer protection to New Zealanders, particularly those most at risk of COVID-19;

1.3 supporting New Zealand's longer-term approach to reconnecting New Zealand to the rest of the world;

1.4 enabling donation of vaccines bilaterally and through the COVAX Facility to the Pacific and wider;

2 **noted** that the context has changed since the Vaccine Strategy was originally developed, and while global supply is increasing, demand and competition for favourable vaccine doses remains high;

3 **noted** that the portfolio of vaccines will need to facilitate ongoing vaccination beyond 2021 in the context of the overall immunisation strategy to ensure that uptake is maximised and to best protect the health outcomes of New Zealanders;

4 **noted** that the portfolio will need to remain flexible to ensure no unnecessary wastage of vaccines that could otherwise be donated or delivery diverted to countries in need of vaccine;

5 **agreed** that New Zealand continue to support the Cook Islands, Niue, and Tokelau to access sufficient vaccines to cover their ongoing immunisation needs in 2022;

6 **agreed** that New Zealand will work with other donors to support Samoa, Tonga, Tuvalu and Fiji to access sufficient vaccines to cover their ongoing immunisation needs in 2022;

7 **noted** there is almost certainly going to be a need for ongoing immunisation in 2022 (and possibly onwards) to continue to improve uptake:

7.1 as more population groups become eligible (for example paediatric groups) or more people age into the existing groups;

7.2 as more people become motivated to access vaccination (due to opening borders);

7.3 through ongoing work to improve access for unvaccinated population groups;

7.4 by potentially providing a vaccine for people unable or unwilling to take an mRNA vaccine;

8 **agreed** that officials progress negotiations with vaccine suppliers for additional vaccines where appropriate to ensure that the portfolio can continue to support immunisation needs in New Zealand and the Pacific, as well as supporting globally equitable access to COVID-19 vaccines;

9 [redacted]

10 **noted** that Pfizer has approached the Ministry of Health with a proposed amendment to our current APA, [redacted]

11 **agreed** to delegate any future purchasing decisions to Vaccine Ministers, with further advice to be provided following completion of negotiations, expected in early September 2021;

12 **agreed** that officials provide further advice to Vaccine Ministers on the purchase of COVID-19 therapeutics by the end of September 2021;

13 **noted** that the COVAX Facility procurement model will be updated for 2022, and officials will report back to Vaccine Ministers with advice regarding our ongoing participation once we have received revised Terms and Conditions;

14 [redacted]

15 [redacted]

16 **noted** the Minister of COVID-19 Response has asked officials to provide advice on ensuring that New Zealand has access to therapeutics to help minimise the health impacts of COVID-19;

17 **agreed** that the tagged contingency also be made available to secure access to therapeutics should additional funding be required;

18 **approved** the following changes to the tagged contingency "Minimising the health impacts of COVID-19 – Tagged Operating Contingency" in Vote Health to give effect to the decisions in paragraphs 15 and 17 above:

Vote Health **Minister of Health**	$m – increase/(decrease)			
	2021/22	2022/23	2023/24	2024/25 & Outyears
Minimising the health impacts of COVID-19 – Tagged Operating Contingency	[redacted]	[redacted]	-	-

19 **agreed** that the increases in paragraph 18 above be charged against the COVID-19 Response and Recovery Fund with a corresponding impact on the operating balance and net core Crown debt;

20 **noted** that funding is ring-fenced for implementing the COVID-19 Vaccine Strategy and cannot be transferred to other appropriations, and that once the COVID-19 public health response winds up, any remaining funding will be returned to the Crown;

21 **authorised** Vaccine Ministers to draw down on the tagged operating contingency funding referred to in paragraph 18 above;

22 **noted** the options set out in the paper attached to CAB-21-MIN-0350 for determining the total delivery of the Pfizer vaccine in 2021 and for reprofiling the delivery of the vaccine;

23 **authorised** a group of Ministers, comprising the Prime Minister, the Minister of Finance and the Minister for COVID-19 Response, to have Power to Act to take decisions on determining the total delivery of the Pfizer vaccine in 2021 and reprofiling the delivery of the vaccine, taking the following principles into account:

23.1 aiming for 90 – 95% uptake;

23.2 provision for potential booster shots;

23.3 provision for extension of eligibility to other potential population groups;

24 **noted** that even with delivery profiled across Quarter 4 2021, and taking into account planned donations to the Pacific, it is possible doses could go to waste;

25 [redacted]

Michael Webster
Secretary of the Cabinet

MINISTRY OF HEALTH
MANATŪ HAUORA

Briefing

Supply agreement for the purchase of additional COVID-19 vaccines from Pfizer New Zealand Ltd in 2022

Date due to MO:	15 October 2021	**Action required by:**	20 October 2021
Security level:	Commercially Sensitive	**Health Report number:**	HR20211937

To:

Rt Hon Jacinda Ardern, Prime Minister
Hon Grant Robertson, Minister of Finance
Hon Chris Hipkins, Minister for COVID-19 Response
Hon Andrew Little, Minister of Health
Hon Nanaia Mahuta, Minister of Foreign Affairs
Hon Dr Megan Woods, Minister of Research, Science and Innovation
Hon Aupito William Sio, Minister for Pacific Peoples
Hon Dr Ayesha Verrall, Associate Minister of Health
Hon Peeni Henare, Associate Minister of Health

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Director-General of Health	[redacted]
Maree Roberts	Deputy Director-General, System Strategy and Policy	[redacted]

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

This is the exhibit marked "**ARB-10**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

Supply agreement for the purchase of additional COVID-19 vaccines from Pfizer New Zealand Ltd in 2022

Security level:	Commercially Sensitive	**Date:**	15 October 2021
To:	Rt Hon Jacinda Ardern, Prime Minister Hon Grant Robertson, Minister of Finance Hon Chris Hipkins, Minister for COVID-19 Response Hon Andrew Little, Minister of Health Hon Nanaia Mahuta, Minister of Foreign Affairs Hon Dr Megan Woods, Minister of Research, Science and Innovation Hon Aupito William Sio, Minister for Pacific Peoples Hon Dr Ayesha Verrall, Associate Minister of Health Hon Peeni Henare, Associate Minister of Health		

Purpose of report

1. To seek your agreement to an amendment to the existing advance purchase agreement (APA) with Pfizer New Zealand Ltd (Pfizer) for the purchase of an additional 4.7 million doses of COVID-19 vaccine in 2022.
2. We also seek agreement to appropriate funds for the purchase.

Summary

3. We anticipate that that there is likely to be a need for ongoing immunisation in 2022 for those who did not access a vaccine in 2021, where there is extended eligibility (children under 12 years of age) and for a potential booster programme, if evidence determines this is required.
4. Given efficacy data, and public perception of a highly safe and effective vaccine resulting from New Zealand's Pfizer-based approach to date, we expect to continue to need an mRNA vaccine over the longer term.
5. Following Cabinet approval to progress negotiations to secure additional COVID-19 vaccines in 2022, officials have finalised negotiations with Pfizer to secure an additional 4.7 million Pfizer doses for delivery in 2022 through an amendment to our current APA.
6. The price per dose in 2022 is [redacted], with a total cost of [redacted]
7. We are seeking your agreement to purchase 4.7 million doses of the Pfizer vaccine because:

a. this would provide continuation of supply of an mRNA vaccine (specifically Pfizer's vaccine) for the CVIP for those who do not access a vaccine in 2021 and who may require a third dose in 2022;

b. we have a strong working relationship with Pfizer already, have confidence in Pfizer's ability to manufacture and deliver a high-quality vaccine; and

c. we have worked closely with the Ministry for Foreign Affairs and Trade, Pharmac, and [redacted]

8. If you agree to this purchase, and the Minister of Finance agrees to the indemnity required by Pfizer, the Director-General will sign and execute the amendment. Following this, officials recommend that you announce up to 4.7 million doses have been secured to support the COVID-19 Immunisation Programme, but do not recommend communicating the delivery dates until they have been confirmed closer to the time of delivery.

9. All communication will be required to be carried out in coordination between New Zealand and Pfizer.

Recommendations

We recommend you:

a) **Note** that in May 2020, Cabinet agreed to the COVID-19 Vaccine Strategy [CAB-20-MIN-0229 refers] which enabled New Zealand to successfully secure access to four COVID-19 vaccines and enabled the roll-out of the Pfizer vaccine.

b) **Note** that the Vaccine Strategy continues to be applied in a changing context to ensure New Zealanders are best protected against COVID-19.

c) **Note** that there is almost certainly going to be a need for ongoing immunisation in 2022 for those who did not access a vaccine in 2021, where there is extended eligibility (paediatric doses) and for a potential booster programme, if evidence determines this is required.

d) **Note** that on 30 August 2021, Cabinet agreed that New Zealand will continue to support the Cook Islands, Niue, and Tokelau, and work in coordination with other donors to support Samoa, Tonga, Tuvalu and Fiji to access sufficient vaccines to cover their ongoing immunisation needs in 2022 [CAB-21-MIN-0350 refers].

e) **Note** that to support ongoing uptake in New Zealand and immunisation needs in the Pacific in 2022, we continue to need access to an mRNA vaccine over the longer term.

f) **Note** that at this stage, there is not enough data to predict if or when any booster doses will be required to maintain high vaccine effectiveness and protection against COVID-19 for the general population.

g) **Note** we have negotiated with Pfizer for the purchase of 4.7 [redacted]

h) **Note** that this purchase enables us to support ongoing uptake in the population, and secures access to sufficient doses in the event that boosters are required.

   i. in combination with doses expected to not to be utilised in 2021, this purchase would support booster doses at 9 months from the second dose, as well as paediatric doses from Q1 2022.

   ii. this purchase also enables us to continue to support immunisation programmes in the Cook Islands, Niue and Tokelau, as well as Samoa, Tonga, Tuvalu and Fiji, in coordination with other donors, if required.

i) **Note** the negotiations have been carried out by officials from the Ministries of Health and Foreign Affairs and Trade, and Pharmac, with the support of external legal counsel Bell Gully.

j) **Note** that in August 2021, Cabinet [CAB-21-MIN-0350 refers]:

   i. agreed to increase the tagged contingency "Minimising the he[redacted]s of COVID-19 – Tagged Operating Contingency" by an additional [redacted] to secure supply of an mRNA vaccine; and

   ii. authorised Vaccine Ministers to draw down on the tagged operating contingency funding.

k) **Agree** subject to the agreement of the Minister of Finance to grant the indemnity in favour of Pfizer, the Director-General of Health, on behalf of the Crown, will sign the proposed amendment to the APA to purchase 4.7 million additional doses of Pfizer's COVID-19 vaccine to be delivered in 2022. **Yes/No**

l) [redacted]ur agreement to recommendation k) above, to draw down [redacted] from the 'Minimising the health impacts of COVID-19 – [redacted]ontingency'. **Yes/No**

m) **Approve** if you agree to the recommendation l) above, the following changes to the appropriations to provide for the decision, with a corresponding impact on the operating balance and net core Crown debt as follows: **Yes/No**

Vote Health **Minister of Health**	$m – increase/(decrease)			
	2021/22	2022/23	2023/24	2024/25 & Outyears
Multi-Category Expenses and Capital Expenditure: Implementing the COVID-19 Vaccine Strategy MCA **Non-Departmental Output Expense:**	[redacted]	-	-	-

Purchasing Potential and Proven COVID-19 Vaccines and Other Therapeutics				

n) **Agree** that the changes to appropriations for 2021/22 above be included in the 2021/22 Supplementary Estimates and that in the interim the increase be met from Imprest Supply. **Yes/No**

o) **Note** that Treasury officials are separately seeking agreement from the Minister of Finance to extend the indemnities in favour of Pfizer and others included in the APA to include these additional doses.

p) **Note** that if the Minister of Finance agrees to extend the indemnities, then he will be invited to co-sign the amendment to the APA in respect of the indemnity obligations within the amendment in favour of Pfizer and others.

q) **Agree** that, prior to any future purchases of Pfizer COVID-19 vaccines from Pfizer or any other party (whether under this APA or otherwise) and any future donations of Pfizer COVID-19 vaccines, the Minister of Finance's prior approval must be obtained, in order for the Minister of Finance to consider the impact of that purchase/donation on those indemnity obligations. **Yes/No**

r) **Note** that officials recommend communicating this additional purchase once Pfizer have countersigned the amendment agreement.

Rt Hon Jacinda Ardern

Prime Minister

...../...../.....

Hon Grant Robertson

Minister of Finance

...../...../.....

Hon Chris Hipkins

Minister for COVID-19 Response

...../...../.....

Hon Andrew Little

Minister of Health

...../...../.....

Hon Nanaia Mahuta

Minister of Foreign Affairs

...../...../.....

Hon Dr Megan Woods

Minister of Research, Science, and Innovation

...../...../.....

Hon Aupito William Sio

Minister for Pacific Peoples

...../...../.....

Hon Dr Ayesha Verrall

Associate Minister of Health

...../...../.....

Hon Peeni Henare

Associate Minister of Health

...../...../.....

Dr Ashley Bloomfield

Director-General of Health

...../...../.....

Supply agreement for the purchase of additional COVID-19 vaccines from Pfizer New Zealand Ltd in 2022

Context

New Zealand has purchased a portfolio of vaccines and has sufficient volumes to deliver a Pfizer-based COVID-19 Immunisation Programme in 2021

1. New Zealand has purchased a portfolio of COVID-19 vaccines (Pfizer, AstraZeneca, Janssen, and Novavax) to manage risk and uncertainty, and is rolling out a Pfizer based COVID-19 Vaccine and Immunisation Programme (CVIP).

2. New Zealand has secured 10.88 million doses of the Pfizer vaccine for delivery in 2021, which is sufficient to fully vaccinate all eligible people this year (currently 4.2 million people), including with any extensions in eligibility (460,000 aged between 5 and 11). This means we will likely have a surplus of at least 2.2 million doses (assuming 95 percent uptake in people aged 12 and over). See table 1 below for Pfizer's indicative delivery schedule.

Table 1: Pfizer's expected delivery schedule across 2021

	February - September	October	November	December
Doses	[redacted]	[redacted]	[redacted]	[redacted]

**this amount is an estimate and yet to be confirmed by Pfizer*

3. The shelf life of the Pfizer vaccine has increased from six to nine months which will mean that at least 1.6 million of the 2.2 million surplus doses from 2021 will be available for use up until June 2022.

There is almost certainly going to be a need for ongoing immunisation in 2022 and Cabinet has agreed to progress negotiations with Pfizer for supply in 2022

4. We anticipate that that there is likely to be a need for ongoing immunisation in 2022 for those who did not access a vaccine in 2021, where there is extended eligibility (paediatric doses) and for a potential booster programme, if evidence determines this is required.

5. In 2022, CVIP should continue to prioritise maximising population coverage in eligible groups (in particular those who are yet to receive a vaccine), recognising that we anticipate that the last 20 percent of people to get vaccinated will be harder because they face more barriers to access and may be less motivated to get vaccinated.

6. [redacted]

7. Given efficacy data, and public perception of a highly safe and effective vaccine resulting from New Zealand's Pfizer-based approach to date, we expect to continue to need an mRNA vaccine over the longer term.

8. On 30 August, Cabinet agreed to increase the tagged contingency "Minimising the health impacts of COVID-19 – Tagged Operating Contingency" by an [redacted], and that officials progress negotiations with vaccine suppliers for additional vaccines where appropriate to ensure that the portfolio can continue to support immunisation needs in New Zealand and the Pacific [CAB-21-MIN-0350 refers]. Cabinet also delegated any future purchasing decisions to Vaccine Ministers.

We have an opportunity to purchase an additional 4.7 million doses of Pfizer for delivery in 2022

Purchasing these additional doses would enable ongoing uptake in 2022

9. Although supply in 2022 is expected to be less constrained than 2021 and should be able to match the desired CVIP more adequately, it is important to amend our APA now to allow for additional advance purchases for delivery in 2022 to avoid delayed access.

10. Officials have finalised negotiations with Pfizer New Zealand Ltd (Pfizer) to secure an additional 4.7 million Pfizer doses for delivery in 2022. This paper outlines the terms and conditions for the purchase of additional doses in 2022. Purchasing doses for 2022 ensures that we maintain a portfolio of vaccines, including a mRNA option.

11. The price per dose is [redacted], a total cost of [redacted]

12. Assuming a surplus of 2.2 million doses at the end of 2021, securing access to 4.7 million additional doses for delivery in 2022 would cover:

    a. children aged 5 to11;

    b. children who are 4 turning 5 who will become eligible;

    c. all people who were eligible in 2021 but are not vaccinated (ie, 5 percent of eligible people are unvaccinated in 2022 based on a 95 percent uptake assumption for 2021;

    d. eligible population who have received two doses receive a third dose if required;

    e. children who are four turning five in Polynesia and if a third dose is required;

    f. a 250,000-dose contingency to manage uncertainty around uptake and wastage assumptions and potential demand from people returning or entering New Zealand who are unvaccinated.

Further evidence is still needed to support a third dose

13. While we are proposing to purchase sufficient volumes of Pfizer to enable every eligible person a third dose, introducing a third dose in the CVIP should be firmly evidence-driven and targeted to the population groups in greatest need.

14. Evidence regarding the need for a third dose of the Pfizer vaccine is still very emergent. Further science and clinical advice would be required alongside approval from Medsafe before any third dose is able to be offered. This approval would also set a minimum interval between second and third doses (advice would be sought from the COVID-19 Vaccine Technical Advisory Group (CV TAG) on the optimal interval timing.

15. While there is currently insufficient evidence to support widespread need for a third dose, there is some evidence of waning immunity in those who received the vaccine in

April this year. We expect to have a clearer understanding of the need for third doses over coming months and we will continue to monitor the evidence as a priority.

16. Pfizer has indicated that it intends to make a submission to Medsafe in October 2021 for the use of booster doses across all current eligible population groups. Regulators have taken varying approaches to date, with boosters approved for everyone above 16 in some jurisdictions (Israel), or only for elderly and immunocompromised in other jurisdictions (US).

17. Under the terms of the amendment, no 'original doses' which are the same as doses received in 2021 will be shipped until Medsafe approval for the use of the Pfizer vaccine as a booster dose has been granted.

18. Several jurisdictions, including the UK, Australia and the EU, have purchased additional Pfizer vaccine supply for 2022/2023[1], including for potential future booster campaigns. The UK has already begun rolling out third doses of the Pfizer or Moderna vaccine to immunocompromised and at-risk adults.

A Medsafe decision is needed for any extensions in eligibility

19. Officials anticipate that eligibility could be extended to include those aged 5 to 11 years early 2022, subject to Pfizer submitting data for Medsafe's assessment and approval. Purchasing additional vaccines for 2022 means we will have access to a paediatric vaccine for this age group.

20. Pfizer has noted in negotiations that a paediatric version of the vaccine for children 11 and under is under development, which would require establishment of a new global supply chain and would be subject to a new submission to Medsafe. The terms of the amendment to the APA incorporate an option for the Crown to update its purchase order with Pfizer to switch out some of its doses for paediatric doses, however a transition period of no less than [redacted] may apply to accommodate Pfizer's global production scale-up for the new vaccine.

21. This means even if approved in late 2021 or early 2022, a paediatric version of the vaccine may not be available in New Zealand until [redacted] 2022. Pfizer has stated this will be applicable globally, and officials consider that this is a risk that will need to be managed through our portfolio of COVID-19 vaccines.

22. Officials will provide advice following a recommendation from Medsafe on immunisation of 5 to 11 year olds. New Zealand and other countries may seek to vaccinate this age group using the current vaccine, at a lower dose. There are regulatory and administration issues that would need to be worked through before a decision on this could be made.

Although we are purchasing additional Pfizer doses, having access to a range of vaccines is essential

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[1] **a. The United Kingdom has purchased an additional 35 million doses for the second half of 2022.**

b. Australia has purchased an additional 60 million doses for 2022 and 25 million doses for 2023.

c. The European Union has signed agreement to purchase 900 million doses with an option for a further 900 million.

23. [redacted]

24. [redacted]

We recommend purchasing these additional doses of Pfizer's vaccine

25. We are seeking your agreement to purchase 4.7 million doses of the Pfizer vaccine because:

    a. this would provide continuation of supply of an mRNA vaccine (specifically Pfizer's vaccine) for the CVIP for those who do not access a vaccine in 2021 and who may require a third dose in 2022;

    b. we have a strong working relationship with Pfizer already, have confidence in Pfizer's ability to manufacture and deliver a high-quality vaccine; and

    c. we have worked closely with the Ministry for Foreign Affairs and Trade, Pharmac, and [redacted]

26. This purchase will be part of our COVID-19 vaccine portfolio, which continues to support ongoing supply of vaccines to support our immunisation needs, and manages downstream risks, including a sole reliance on Pfizer for COVID-19 vaccines.

Officials have negotiated updated terms and conditions with Pfizer

27. The negotiation priorities agreed by Vaccine Ministers on 13 August 2021 [HR-2021-1824 refers] have guided the negotiations with Pfizer for doses in 2022. This section provides commentary on the updated terms and conditions in the amendment to the APA against our negotiation priorities.

28. [redacted]

29. [redacted]

[redacted]

Under the amendment, we can access an adapted product

30. The negotiated terms allow us to access updated vaccine (to address COVID-19 variants or new formulations), and a paediatric-specific vaccine, should these become available. It does not appear that New Zealand's regulatory process will be prioritised, and will likely follow approval in the US and EU. This is not unexpected given that we are small country and Pfizer tends to submit its regulatory applications individually to manage risk.

31. Supply, and subsequent payment for doses intended as boosters are subject to regulatory approval to extend the indication of Pfizer's vaccine to include use as a third dose. This would not capture updated versions of the vaccine or paediatric doses, which would require a separate approval, [redacted]

The scope of the indemnity has increased

32. The indemnity clause under the amendment reads the same as that granted for the original APA, but is applied in an updated context because the additional doses of vaccine are proposed to potentially be used as booster vaccine, which has not yet been approved by Medsafe. Additionally, there is the potential for supply of an updated or paediatric vaccine.

33. [redacted]

34. [redacted]

35. [redacted]

36. [redacted]

The bulk of the 2022 contract is the same as the existing contract

37. [redacted]

38. [redacted]

39. [redacted]

40. [redacted]

Delivery Schedule

41. [redacted]

42. The interim delivery schedule for these doses in 2022 as follows:

[redacted]

[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

43. However, this delivery schedule will ensure that supply is available early in 2022 (in addition to doses remaining from 2021). Receiving a portion of doses later in the year increases the likelihood of New Zealand accessing paediatric doses or updated versions of the vaccine.

44. [redacted]

45. [redacted]

46. [redacted]

Planning is now underway to ensure these doses can be utilised

47. The Ministry of Health is working on the future COVID-19 immunisation strategy. This will include not only consideration of future COVID-19 vaccine needs but also other vaccine requirements, particularly those who need to continue high levels of protection for New Zealanders such as influenza and measles. It will also look at the delivery of an overall integrated immunisation schedule. This work will cover, policy, purchasing and delivery options.

48. It is also expected that the roles and responsibilities for future purchasing will look different following Cabinet's decision on the implementation of the Health and Disability System Review.

49. The Ministry will continue to seek advice from the CV TAG on the evidence to support future immunisation needs, specifically for children and with respect to booster vaccinations.

50. In parallel to planning for 2022, the CVIP is in the process of securing sufficient consumables (including needles, syringes, and diluent) to support the use of these additional doses from Q1 2022.

51. Our existing Ultra Low Temperature (ULT) storage can store up to 4 million doses. There is some risk that we could end up with surplus doses that would exceed our ULT capacity. [redacted]

Process for extending eligibility or introducing a third dose or updated vaccine

52. Before Cabinet can consider extending eligibility, or introduce a third dose or updated vaccine into the programme, Pfizer must submit an application to Medsafe to seek approval. Any application will be prioritised by Medsafe and Pfizer has indicated its intention to submit an application for paediatric doses (5-11) in October, with an application for booster doses [redacted]

53. If the Pfizer vaccine is approved by Medsafe for use in a broader capacity, we would seek agreement from Cabinet to use the vaccine with supporting advice from the CV TAG.

This purchase will continue to support New Zealand's role as a contributor to the global response to the pandemic

54. On 30 August, Cabinet agreed to continuing to support the Cook Islands, Niue, and Tokelau to access sufficient vaccines to cover their ongoing immunisation needs in 2022 [CAB-21-MIN-0350 refers] and to work with other donors to support Samoa, Tonga, Tuvalu and Fiji to access sufficient vaccines to cover their ongoing immunisation needs in 2022.

55. Purchasing additional Pfizer vaccine will enable us to continue to support Polynesia and Fiji to access vaccine for their eligible population.

56. It would also be possible to donate surplus vaccine to the COVAX Advance Market Commitment (AMC) for distribution to developing countries more widely. However, as above, we expect global vaccine supply will improve next year and dose donation will therefore become a less critical supply source for developing countries.

Equity

57. Ongoing access to COVID-19 vaccines is essential to maximise uptake, it also ensures that we have sufficient supply for those who have not accessed a vaccine in 2021 such as children.

58. Ensuring that the CVIP can progress at as high a rate as possible is crucial to ensure that vulnerable populations can be protected from COVID-19.

59. Availability of vaccines to support booster doses if needed will ensure the most vulnerable will have access to the best protection available to prevent against severe health outcomes from COVID-19.

60. There is some risk that purchasing booster doses while some countries are yet to have access to primary courses could be perceived negatively globally. Officials consider that New Zealand's support for the Pacific and commitment to continue to do so, as well as our ongoing contributions to COVAX, reduces this risk.

We recommend drawing down funding from the tagged contingency to meet the cost of the purchase

61. The total cost for all 4.7 million doses is [redacted]

62. On 30 August, Cabinet agreed to increase the tagged contingency by an additional [redacted] to secure supply of an mRNA vaccine through 2022 and 2023 [CAB-21-MIN-0350 refers] and authorised Vaccine Ministers to draw down on the tagged operating contingency funding.

63. A draw down from the tagged contingency in the 2021/22 financial year is required to cover the costs of these vaccine doses.

Communications

64. Officials recommend that you announce up to 4.7 million doses have been secured to support the COVID-19 Immunisation Programme following execution of the amendment agreement. Officials do not recommend communicating the delivery dates until they have been confirmed closer to the time of delivery [redacted]

65. All communication is required to be carried out in coordination between New Zealand and Pfizer.

Next steps

66. Subject to your agreement to the proposed amendment to our APA with Pfizer, and the Minister of Finance's agreement to grant the indemnity, the Director-General of Health

and the Minister of Finance will be invited execute the amendment on behalf of New Zealand

Annexes

1. Annex One: Proposed amendment to APA
2. Annex Two: Assessment of amendment to APA against negotiation priorities

ENDS.

"ARB-11"

This is the exhibit marked "**ARB-11**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

Appendix X

COVID-19 Vaccine Portfolio Update – 12 November 2021

Date:	11 November 2021
To:	Prime Minister Jacinda Ardern and COVID-19 Vaccine Ministers
From:	Maree Roberts, Deputy Director-General, System Strategy and Policy
Subject:	COVID-19 Vaccine Portfolio Update

Purpose of report

1. This memo provides an update on the COVID-19 Vaccine Portfolio and seeks your agreement to:
   a. the preferred delivery schedule for Pfizer's booster and paediatric doses
   b. the preferred option for an alternative vaccine candidate for managing downstream risk in the portfolio in 2022.

Background

2. COVID-19 vaccine purchasing decisions to date have been made under the COVID-19 Vaccine Strategy (Vaccine Strategy) agreed by Cabinet in May 2020. The objective of the Vaccine Strategy was to secure access to sufficient quantities of safe and effective COVID-19 vaccines, in order to implement a preferred immunisation programme at the earliest possible time [CAB-20-MIN-0229 refers].

3. New Zealand purchased a portfolio of vaccines to manage the risk of vaccine development or supply failure. To date the COVID-19 Immunisation Programme (the Programme) has been based solely around Pfizer's vaccine, however the portfolio continues to play a significant role in managing risk, and potentially increasing rates of overall vaccine uptake.

Current Portfolio situation

Table 1. Current expected vaccine portfolio delivery schedule (in doses)

Vaccine supplier	Q4 2021	Q1 2022	Q2 2022	Q3 & Q4 2022
Pfizer	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

4. Pfizer's vaccine continues to be primary vaccine in the Programme; however, 100,000 doses of AstraZeneca's vaccine will be available from late November for those unable or unwilling to receive Pfizer's mRNA vaccine. Further doses be may available through this route if uptake is high.

5. As at 8 November 2021, 89% of eligible New Zealanders (aged 12 and up) have received a single dose of Pfizer's vaccine and 78% are fully vaccinated. A small number of immunocompromised people are now able to access a third dose to improve their immune response.

6. The focus of the Programme is now shifting to further immunisation needs in late 2021 and 2022, and the role of the vaccine portfolio is to support those needs. Key areas of focus include:

   a. ongoing improvements in uptake across New Zealand

   b. booster doses for eligible groups people (aged 18 and above)

   c. paediatric doses for eligible groups (aged 5-11), subject to Medsafe approval and clinical advice

   d. ongoing support to enable Polynesia and the Realm to implement their vaccination programmes (which may include booster doses and paediatric vaccinations).

Pfizer's delivery schedule

7. On 8 November, Medsafe approved the use of Pfizer's vaccine as a third 'booster' dose at least 6 months following the second dose in individuals aged 18 and over. The COVID-19 Vaccine Technical Advisory Group (CV TAG) has provided clinical advice which will support a decision by Cabinet on 15 November 2021.

8. Medsafe is also currently reviewing an application from Pfizer for the use of a new version of its vaccine developed specifically for use in paediatrics (5-11 years of age). The timeline for this decision is unknown, and will depend on how comprehensive the application by Pfizer is.

9. While decisions have not yet been made regarding booster doses and paediatric doses, officials are working with Pfizer to ensure doses will be available to support the approach taken by the Programme. Early modelling has been generated to forecast demand and supply needs.

10. The current modelling assumes (for New Zealand, the Realm, and Polynesia):

    a. immunisation of all 5-11s in Q1 2022

    b. priority access to booster doses for high risk groups in late Q4 2021 and Q1 2022

    c. booster doses for the eligible population (aged 18 and above) before the end of Q2 2022.

11. Based on the current modelling, changes to the expected delivery schedule will need to be agreed between Pfizer and officials to enable the proposed rollout. A total of 1.25 million doses of paediatric vaccine would be required in Q1 2022, and an minimum additional [redacted] doses of Pfizer's adult vaccine would be required to be brought forward from the second half of 2022 into Q1 and Q2 to support booster doses in the eligible population. However, fewer doses for the 5-11 year olds may be needed, depending on the clinical recommendations and data provided.

12. These would be the minimum amendments to the delivery schedule to optimise delivery, and the Programme has advised that further doses received early would allow greater operational

control, so long as the storage capacity limits are not exceeded (approximately four million doses centrally).

13. [redacted]

Table 2. Projected vaccine utilisation in 2022 (in doses)

	Q1 2022	Q2 2022
Booster doses (NZ)	[redacted]	[redacted]
Booster doses (Realm & Polynesia)	[redacted]	[redacted]
Paediatric doses (NZ)	1 million	-
Paediatric doses (Realm & Polynesia)	130,000	-

Table 3. Projected vaccine supply needs in 2022 (in doses)

Current expected delivery schedule			
	Supply available end of 2021	Q1 2022	Q2 2022
Current expected delivery schedule	[redacted]	[redacted]	[redacted]
Required delivery schedule			
	Supply available end of 2021	Q1 2022	Q2 2022
Adult doses	[redacted]	[redacted]	[redacted]
Paediatric doses	[redacted]	[redacted]	[redacted]

14. [redacted]

[redacted]

15. [redacted]

[redacted]

16. [redacted]

Officials are seeking your agreement to begin negotiating an updated delivery schedule with Pfizer

17. Based on the modelling outlined above, we are seeking your agreement to request access from Pfizer to:

    a. [redacted] paediatric doses as early as possible [redacted] subject to Medsafe approval and clinical advice on the recommendations for this age group

    b. Access to at least an additional [redacted] doses of the original vaccine (for those aged 12 and above) [redacted]

[redacted]

18. [redacted]

19. [redacted]

20. [redacted]

[redacted]

21. [redacted]

22. [redacted]

23. [redacted]

24. [redacted]

25. [redacted]

26. [redacted]

27. [redacted]

28. [redacted]

29. [redacted]

30. [redacted]

31. [redacted]

32. [redacted]

[redacted]

33. [redacted]

34. [redacted]

35. [redacted]

36. [redacted]

37. [redacted]

Options for supporting the Programme in 2022

Option 1) Seek access to an optimal delivery schedule of doses of Pfizer's vaccine

38. Sufficient vaccine supplies are required to support the potential use of booster and paediatric vaccines from late Q4 to the end of Q2 2022. The Programme remains primarily Pfizer based and the preferred option is to secure sufficient and timely access to doses of Pfizer's vaccine to support this. We are seeking your agreement to request access from Pfizer to:

    a. [redacted] paediatric doses as early as possible [redacted], subject to Medsafe approval

    b. access to at least an additional [redacted] doses of the original vaccine (for those aged 12 and above) [redacted]

39. [redacted]

40. [redacted]

41. [redacted]

42. [redacted]

43. [redacted]

Next steps

44. If you agree, officials will progress negotiations with Pfizer to secure:

    a. [redacted] million paediatric doses as early as possible [redacted] subject to Medsafe approval

    b. access to at least an additional [redacted] doses of the original vaccine (for those aged 12 and above) [redacted]

45. [redacted]

Recommendations

It is recommended that you:

1.	note	that to date the COVID-19 Immunisation Programme has been based solely around Pfizer's vaccine, however the portfolio continues to play a significant role in managing risk, and potentially increasing rates of overall vaccine uptake.
2.	note	that on 8 November, Medsafe approved the use of Pfizer's vaccine as a third 'booster' dose at least 6 months following the second dose in individuals aged 18 and over. The COVID-19 Vaccine Technical Advisory Group (CV TAG) has provided clinical advice which will support a decision by Cabinet on 15 November 2021.
3.	note	that Medsafe is also currently reviewing an application from Pfizer for the use of a new version of its vaccine developed specifically for use in paediatrics (5-11 years of age). The timeline for this decision is unknown, and will depend on how comprehensive the application by Pfizer is.
4.	note	that based on current modelling, changes to the expected delivery schedule will need to be agreed between Pfizer and officials to enable the proposed rollout of booster and paediatric doses.

5.	agree	that to support the potential rollout of booster and paediatric vaccines, officials request access from Pfizer to: a. [redacted] million paediatric doses as early as possible [redacted] subject to Medsafe approval b. at least an additional [redacted] doses of the original vaccine (for those aged 12 and above) [redacted]
6.	agree	[redacted]
7.	agree	[redacted]
8.	agree	[redacted]

"ARB-12"

From: [redacted]
Sent: Monday, 15 November 2021 11:43:37 AM
To: [redacted]
Subject: Delivery Schedule Preference for 2022

Hi [redacted]

Hope you had a great weekend.

I am following up after our discussion last week following confirmation from our Ministers about the delivery schedule preference for next year's doses.

As discussed, we would like to amend our current delivery schedule (outline in the amendment to the APA):

Vaccines	Q1 2022	Q2 2022
	[redacted]	[redacted]

To the delivery schedule outlined below:

Vaccine type	Q1 2022	Q2 2022
Paediatric version	1.25 million doses	-
Current formulation	[redacted]	

As noted on the phone, the delivery of the paediatric doses would ideally be as early as possible and across Q1 (subject to Medsafe approval). The [redacted] additional 'adult' doses would ideally be in Q1 and early Q2.

Happy to discuss further on the phone or at our regular meeting on Wednesday.

Kind regards,

[redacted]

[redacted]
Principal Advisor, System Enablers | System Strategy & Policy | Ministry of Health | New Zealand
[redacted]

MINISTRY OF HEALTH
MANATŪ HAUORA

This is the exhibit marked "**ARB-12**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

"ARB-13"

From: [redacted]
Sent: Friday, 10 December 2021 8:39:33 AM
To: [redacted]
Cc: [redacted]
Subject: Confirmation of paediatric dose allocation

[redacted]

Paediatric dose allocation

As discussed in our meeting last week, under clause 1.8(f) of the fourth amendment to the manufacture and supply agreement with Pfizer:

At the request of the New Zealand Government, we wish to confirm that we will require 1,250,000 (adjusted to match shipment sizes) paediatric doses for use in individuals aged 5-11 years.

For clarity, this would represent 1,250,000 million of the 4,701,060 doses allocated under the fourth amendment of the agreement.

Based on the information you have provided with regards to independent batch testing, delivery of the initial [redacted] doses in the first week of January is optimal.

We would then like to receive a further [redacted] doses in February, and [redacted] doses in March.

For the remaining [redacted] doses, we would like to receive these spread across Q2 2022.

Please let us know if you would like to discuss the delivery schedule in greater detail.

This request is subject to Medsafe approval of the use of the paediatric vaccine in New Zealand.

We will provide a purchase order immediately following Medsafe approval, if and when it is obtained.

Additional adult (12+) doses in Quarter 2

[redacted]

Kind regards,

[redacted]

Principal Advisor, System Enablers | System Strategy & Policy | Ministry of Health | New Zealand

[redacted]

MINISTRY OF HEALTH
MANATŪ HAUORA

This is the exhibit marked "**ARB-13**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

This is the exhibit marked "**ARB-14**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

MINISTRY OF HEALTH
MANATŪ HAUORA

Memo

Variation to the advance purchase agreement with Pfizer: Paediatric delivery schedule

Date:	21 December 2021
To:	Dr Ashley Bloomfield, Director-General of Health
From:	Maree Roberts, Deputy Director-General, System Strategy & Policy
For your:	Action

Purpose of report

1. This memo seeks your agreement to sign a variation to the advance purchase agreement (APA) with Pfizer Inc (Pfizer) which updates the agreement to enable the delivery of Pfizer's paediatric version of its COVID-19 vaccine (for 5 to 11 -year-olds) to New Zealand. The updates include estimated delivery timeframes for 2022 and updated information required to implement the rollout of the paediatric vaccine.

Context

2. To date, the COVID-19 Vaccine Immunisation Programme (CVIP) has been based around Pfizer's vaccine, with AstraZeneca's vaccine available as an alternative. The remaining vaccines in the portfolio (Novavax and Janssen) remain available for possible utilisation to mitigate changes in the pandemic environment and immunisation response.
3. Based on Medsafe approval, eligibility for Pfizer's vaccine was limited to persons 12 years and over, resulting in the inability to provide vaccine-based protection to those under 12 years of age in New Zealand.
4. To offer future protection to 5 to 11-year-olds, and as part of securing an additional 4.7 million doses of Pfizer's vaccine in 2022, officials negotiated advanced access to Pfizer's paediatric vaccine product in October 2021, subject to successful development and Medsafe approval.
5. On 16 December, Medsafe granted provisional consent for the use of Pfizer's paediatric COVID-19 vaccine in children aged 5-11.

New Zealand has access to 1.25 million doses of Pfizer's paediatric vaccine

6. In October 2021, an amendment was made to the Pfizer APA to secure access to an additional 4.7 million doses of Pfizer's vaccine in 2022, which included an option for a portion of these doses to be allocated to the paediatric version of the vaccine. Of the newly purchased 4.7 million doses, Ministry officials have requested 1.25 million doses of the new paediatric product.

7. This is sufficient volume to provide two doses of the vaccine for all children aged 5 to 11 years (467,000) in New Zealand and Polynesia (Cook Islands, Niue, Tokelau, Samoa, Tonga, Tuvalu) as well as for children turning 5 in 2022.

8. The APA in its current form includes an interim delivery schedule for the 4.7 million doses available in 2022, but no details regarding the timing and quantities related to paediatric doses.

A variation to the Pfizer APA is required to confirm these doses

9. Pfizer has provided a proposed variation to the current APA to confirm the quantities of paediatric vaccine allocated and an expected delivery schedule for these doses.

10. The expected delivery schedule is outline below in Table 1, which:

    a. enables early immunisation of the 5 to 11-year-old population from January

    b. provides sustained access to paediatric vaccines to support ongoing uptake, particularly for children turning 5 throughout the year.

Table 1. Expected Delivery Schedule of Pfizer's COVID-19 vaccine in 2022

2022	Q1	Q2	Q3	Q4
Paediatric (5-11) doses	1,150,000	100,000	-	-
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

11. The paediatric version of Pfizer's vaccine currently has a 6-month shelf life, which is expected to result in a 3 to 4-month shelf life upon receipt of the vaccine. The first shipment of [redacted] doses in January will expire 31 March 2022.

12. The delivery schedule negotiated with Pfizer [redacted] aims to manage the risk of expiry and wastage of doses, while ensuring sufficient doses are available to maximise timely uptake.

13. Pfizer has indicated it intends to submit an application to Medsafe in January to extend the shelf life of the paediatric version of the vaccine by three months, which would enable ongoing availability of paediatric doses throughout 2022 for children turning 5.

14. [redacted]

15.

Assurances

16. [redacted]

17. The Minister of Finance is required to co-sign the variation in respect of the indemnity obligations under the APA with Pfizer. This variation does not impact the indemnity, which already covers the use of a paediatric vaccine in New Zealand.

18. The COVID-19 Vaccine Immunisation Programme is preparing for the rollout of the paediatric vaccine. Clinical advice has been sought, the appropriate consumables to administer the paediatric vaccine have been procured, and advice is being sent to Cabinet to consider the use of Pfizer's paediatric vaccine in 5 to 11-year-olds on 20 December.

19. Execution of this variation to the APA will enable the timely supply and access to the vaccine to support a potential rollout in January 2022.

Next steps

20. If you agree to co-sign the amendment to the APA on behalf of the Crown, Pfizer will be invited to countersign, and the updated agreement will enable the delivery of 1.25 million paediatric doses of Pfizer's vaccine in 2022.

Recommendations

It is recommended that you:

1.	note	The updated terms of the APA with Pfizer; including the: a. expected delivery schedule for Pfizer's paediatric version of its COVID-19 vaccine in 2022 b. specifications for Pfizer's paediatric version of its COVID-19 vaccine.	
2.	sign	The attached variation to the APA with Pfizer on behalf of the Crown.	Yes/No

Signature [redacted] Date: 21 DECEMBER 2021

Maree Roberts

Deputy Director-General, System Strategy and Policy

Signature _____ Date: 21 December 21

for Dr Ashley Bloomfield

Te Tumu Whakarae mō te Hauora

Director-General of Health

Commercially Sensitive

Office of the Minister for COVID-19 Response

Cabinet

This is the exhibit marked "**ARB-15**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

Decision to use the COVID-19 Pfizer paediatric vaccine for children aged 5 to 11 years

Proposal

1 This paper seeks agreement from Cabinet on the use of the Pfizer paediatric vaccine for children aged 5 to 11 years, and donation of this vaccine to Polynesian countries.

Relation to government priorities

2 This proposal relates to the Government's priority of continuing to keep New Zealanders safe from COVID-19; and to the Government's priority to make New Zealand the best place in the world to be a child (as articulated in the Child and Youth Wellbeing Strategy).

Executive Summary

3 This paper considers the use of Pfizer's paediatric COVID-19 vaccine for children aged 5 to 11 years, following provisional consent by Medsafe. The COVID-19 Vaccine Technical Advisory Group (CV TAG) has recommended this vaccine is offered to all children 5 to 11 years. The Director-General of Health has accepted the CV TAG advice and recommends that Cabinet agrees to the use of this paediatric vaccine for New Zealand children.

4 CV-TAG have recommended that Pfizer's paediatric vaccine is given as two doses eight weeks apart or at least three weeks apart where there is good reason for a shorter dose interval. They have also recommended that mandates, vaccine certificates or vaccine targets not be used for this age group and children should not be denied access to locations or events or excluded based on their vaccination status.

5 Planning for immunisation of children aged 5 to 11 years is well underway and can commence from 17 January 2022 should you agree to use the vaccine in this group. Supply is expected from early January 2022, and officials will work closely with Pfizer to optimise the delivery schedule to meet New Zealand's needs.

6 Implementing immunisation for children will focus on using the existing infrastructure, service delivery models, vaccinators, and channels in a two-pronged approach from the outset. This will include a broad reach across Aotearoa and a simultaneous, targeted focus on equity, vulnerable communities, and areas with lower vaccination rates. There will be sufficient vaccine supply and provider capacity available to offer COVID-19 immunisation to all children aged 5 to 11 years concurrently, so no sequencing is required.

7 An early and strong focus on working with Māori is especially important. Tamariki Māori have been impacted more by the pandemic than other children and remain at higher risk. Children also make up a higher proportion of the Māori population than for non-Māori. Māori and Pacific children are more likely to live in multigenerational families housed in overcrowded conditions, increasing the risk of transmission.

8 New Zealand continues to play a role internationally, supporting access to vaccines particularly for the six countries in Polynesia. I am now seeking your agreement to donate up to 130,000 doses of Pfizer's paediatric vaccine to the six Polynesian countries, in line with New Zealand's Immunisation Programme.

Background

9 On 3 December 2021, New Zealand moved to the COVID-19 Protection Framework. The system is based on the premise that there will be cases of COVID-19 in the community at any given time, but that we will predominately be managing this with a highly vaccinated population and other public health measures.

10 As COVID-19 vaccines are a critical tool in protecting people from the risks of COVID-19, maximising uptake is a key focus of the Government to keep everyone in New Zealand safe.

11 New Zealand continues to roll out the predominantly Pfizer-based COVID-19 Immunisation Programme (the Immunisation Programme) for those aged 12 years and over, and those aged 18 years and older can access a booster dose at least six months after their second dose. AstraZeneca is also now available for those aged 18 and over.

12 As part of the ongoing rollout of the Immunisation Programme, officials have considered the possible extension of the eligible population to include children 5 to 11 years of age, based on emerging evidence and experience of other countries.

13 Children under 12 years are at lower risk from direct health impacts of COVID-19 than older age groups. However, COVID-19 can have serious health consequences for some children. Children living with pre-existing health conditions or comorbidities have a greater risk of severe disease from COVID-19. Māori and Pacific children are more likely to live in multigenerational families housed in overcrowded conditions, increasing the risk of transmission from other household members. There is also risk of other household members being infected by unvaccinated children, though the risk of transmission from children is lower than from adults.

14 A COVID-19 vaccine for children under 12 years has the potential to keep them safe from COVID-19 and may reduce the risk of transmission of COVID-19 especially in multigenerational and overcrowded households.

15 To support COVID-19 vaccine needs, New Zealand has secured an additional 4.7 million doses of the Pfizer vaccine for 2022. This includes access to 1.25 million doses of Pfizer's paediatric vaccine product, which is sufficient volume for children aged 5 to 11 years in New Zealand (477,000) and in the six Polynesian countries (Cook Islands, Niue, Tokelau, Samoa, Tonga, Tuvalu) to receive a full course (two doses) of the vaccine.

16 It is important to note that the paediatric version is different to the current 'adult' version. The differences include changes to the ingredients and the amount of the ingredients in the vial, including the concentration of mRNA (active ingredient). Therefore, this product is not merely a 'more dilute' version of the adult vial.

17 To date, all decisions on the use of a new COVID-19 vaccine as part of the Immunisation Programme have been informed by the Decision to Use Framework. This considers New Zealand's domestic context, the advice provided by the COVID-19 Vaccine Technical Advisory Group (CV TAG) and the Ministry of Health. The Framework also considers available supply of vaccine, the implementation approach and timing, and our role in supporting international efforts and our Pacific neighbours.

Use of the Pfizer COVID-19 Vaccine in children aged 5 to 11 years

The Pfizer COVID-19 vaccine has been granted provisional approval by Medsafe for children aged 5 to 11 years

18 Before any vaccine is used in New Zealand, it needs to have consent (or provisional consent) from Medsafe (under the Medicines Act 1981). This process provides assurance that medicines meet acceptable standards of safety, quality, and efficacy. In addition, transparency and rigour in the approval process will help to maintain public confidence in the vaccine. A robust regulatory process is key to supporting a successful COVID-19 Immunisation Programme.

19 On 16 December 2021, Medsafe granted provisional consent for the use of the Pfizer COVID-19 paediatric vaccine for children aged 5 – 11 years old. Medsafe's role is to consider whether a vaccine meets high standards for safety, efficacy and quality for a particular group of people.

20 In granting provisional consent, Medsafe has required ongoing provision of information on storage, quality assurance and safety, as use of the vaccine increases globally. These conditions are similar to those for other COVID-19 vaccine products which are newly developed and on which considerable data is being collected as they are being used globally.

The Pfizer paediatric vaccine

21 The Pfizer paediatric vaccine is a lower dose product developed especially for children under 12 years who produce a strong immune response at lower doses than for adults. The 10µg paediatric dose produces similar immune responses in this age group as are seen in the 16-to-25-year age group with the standard 30µg dose. To date, no comparisons have been made to immunise response in those aged 12 to 15 years olds.

22 Clinical trial data have shown the Pfizer paediatric vaccine to have a favourable safety profile in children with mild and self-limiting side effects and good immunity from seven days after the second dose. No vaccine-related serious adverse events have been reported. Further safety data from large scale roll-out of this paediatric vaccine in the United States and Canada are expected in early January 2022.

Expert advice on use of the Pfizer vaccine for children aged 5 to 11 years

23 The CV TAG has recommended that:

23.1 that Pfizer paediatric vaccine be offered to all children aged 5 to 11 years, to be given as two doses eight weeks apart or at least three weeks apart where there is good reason for a shorter dose interval

23.2 mandates, vaccine certificates or vaccine targets must not be used for this age group and children should not be denied access to locations or events or excluded based on their vaccination status

23.3 focus be given to immunisation of Māori and Pacific children, children with high-risk pre-existing conditions and children living with vulnerable people

23.4 focus also be given to improving access and uptake of COVID-19 vaccination and boosters in adults, other childhood immunisation in children, and strengthening public health measures in schools and other education settings

23.5 careful safety monitoring be undertaken with recommendations reviewed as data emerges from the US and Canadian immunisation programmes for children.

24 The Director-General of Health has accepted and is in agreement with this advice, and has asked that CV TAG undertake a formal safety review in February 2022 to confirm the recommended eight week interval between doses.

25 Medsafe has granted provisional approval Pfizer's paediatric vaccine with an interval between the first and second dose of at least 21 days. CV TAG have recommended an eight week interval as the optimal duration between doses for 5-11-year-olds, noting this may improve immunogenicity and reduce side effects. A longer dose interval would also allow greater time to monitor international safety data during the rollout.

Child wellbeing impact assessment

26 Officials have undertaken a Child Wellbeing Impact Assessment (the Impact Assessment) of immunisation for children aged 5 to 11 years, to inform Cabinet's decision and guide implementation to enhance the wellbeing of children in New Zealand, while not jeopardising the rights or wellbeing of any group.

27 The Ministry consulted widely with key agencies to ensure that any paediatric vaccination programme enhances the wellbeing of children in New Zealand, while not jeopardising the rights or wellbeing of any group. Specifically, the Ministry has engaged with the Ministries of Education and Social Development, the Ministries for Māori Development, Pacific Peoples, and Ethnic Communities, the Ministry of Women, Oranga Tamariki, the Office of the Children's Commissioner, and the Office for Disability Issues in this assessment.

28 While COVID-19 is rarely serious or fatal for children, the pandemic has had and will continue to have significant impacts on children's health, education, relationships, development, and lives. The Impact Assessment completed by the Ministry of Health highlighted the following:

28.1 immunisation of the wider population should continue – it is important to protect children and promote their wellbeing

28.2 immunisation of children should proceed and be offered to all aged 5 to 11 years – it adds protection and promotes children's development with or without high levels of population immunisation

28.3 immunisation of tamariki Māori requires high and urgent focus – compared with non-Māori children, Māori have suffered greater pandemic effects, remain at high risk and have a larger child population with 10% of Māori under 5 years old and ineligible for vaccine

28.4 that restrictions for any child based on their vaccination should not outweigh the benefits to their development of full access and participation in education, development, recreation and community activities and public places

28.5 immunisation of children should, where possible, promote whānau wellbeing, be offered in multiple ways to suit a wide range of families and groups, and cater especially for Māori, Pacific peoples, children and families with illnesses and disabilities, children and families living in poverty, and children in the care of Oranga Tamariki.

Obligations under Te Tiriti o Waitangi

29 In adhering to the principles of Te Tiriti o Waitangi, it is essential that immunisation rollout embraces Tino Rangatiratanga, Partnership, Active Protection, Options and Equity. This will include:

29.1 Māori-led approaches for Māori

29.2 partnership between hauora, Māori providers, DHBs, and iwi

29.3 empowering, resourcing and providing training for hauora and Māori providers as early as possible

29.4 strong Māori communications to promote equitable paediatric uptake for Māori

29.5 a clear focus on equitable immunisation outcomes for Māori more generally, including tamariki Māori

29.6 overall, a high and urgent focus on the immunisation of tamariki Māori.

Consistency with WHO guidance

30 The World Health Organization (WHO) issued an Interim statement on COVID-19 vaccination for children and adolescents (updated 29 November 2021). It states that:

30.1 Countries should consider the individual and population benefits of immunising children in their specific epidemiological and social context

30.2 Benefits go beyond direct health benefits – minimising disruptions to education and maintenance of overall well-being, health and safety are important

30.3 Attaining high coverage of high-risk groups such as older people, those with chronic health conditions and health workers, including booster doses, should be prioritised before children and adolescents

30.4 Global sharing through the COVAX facility should be prioritised before vaccination of children and adolescents who are at low risk for severe disease.

31 The advice in this paper, and the Impact Assessment has been informed by is consistent with this WHO guidance. Sharing paediatric vaccine with the countries of Polynesia, as noted below, will support their child immunisation plans.

Supply and uptake considerations

32 There is some uncertainty around the uptake of the vaccine in those aged 5 to 11 years old. Of responders to an October Horizon research poll, 68% (including 51% of Māori 90% of Pacific responders) would definitely or most likely allow children in their care to be immunised. This is an encouraging result as we expect support to grow as the Immunisation Programme rolls out.

33 [redacted]

34 Upon arrival of the Pfizer doses, there is a quality assurance step to ensure the vaccine is fit for purpose before the Ministry of Health takes ownership of the doses from Pfizer. This involves confirming receipt of delivery and that the vaccine has been kept at -70 degrees throughout the shipment, and that there have not been any breakages during transit.

35 The table below outlines theses with anticipated timelines for the first four days following arrival in New Zealand of the first shipment of the Pfizer vaccine.

Day	Step	Temperature
1	Shipment of vaccine arrives in Auckland, and Quality Assurance process completed	-70 degrees
2-3	Shipment of vaccine is prepared for distribution to sites	-70 degrees
4	Vaccination site receive vaccines and consumables	2-8 degrees

36 [redacted], we will be well placed in advance to begin the roll out on the week commencing 17 January if desired.

Proceeding with the rollout of a paediatric programme from 17 January 2022

37 Planning is well underway for the immunisation rollout so there will be minimal delay once decisions have been made on offering the paediatric vaccine. Rollout from the week of 17 January 2022 allows the minimum sufficient time for planning that includes the following:

37.1 Suitability for children is being assessed and guidance developed across the wide range of community-friendly immunisation delivery models that are being used and adapted for different communities and localities. For example, drive-through vaccination suits some families; additional guidance on observation and surrounding facilities and staffing is being developed, and dry runs and trial runs will be needed ahead of "going live".

37.2 Digital records infrastructure is being developed to provide for the paediatric vaccine requirements and allow bookings, adverse event surveillance and user experience surveys. No vaccine passes are planned to be offered at this stage for children 5 to 11 years, although in future children will be able to apply for international vaccine certificates if these are required for travelling.

37.3 Partnership and engagement with Hauora Māori, Pacific providers and family and community groups will facilitate promotion and acceptability of paediatric immunisation approaches.

38 It will be important to maintain focus on adult immunisation and booster uptake. Some communities that are only now reaching high immunisation uptake will be well-represented among parents of 5- to 11-year-olds. Immunisation of children will provide good opportunities to promote whole whānau vaccination, uptake of measles mumps and rubella (MMR), influenza immunisation and other health and social services.

39 Further implementation decisions may be required. To avoid delay, I recommend that the Prime Minister, the Minister of Finance, the Minister for COVID-19 response, and the Minister of Health (the group of Ministers) are granted the power to act to ensure timely decision making (if required) on the use and implementation of Pfizer paediatric vaccine in the COVID-19 Immunisation Programme.

40 Officials will report back to the group of Ministers with power to act over the holiday period on the implementation approach prior to opening up invitations for children aged 5 to 11 years, this will reflect lessons learned in the initial phase of the vaccination programme and an update on the ongoing co-design process currently underway with hauora providers and iwi representatives.

Implementation

Immunisation Implementation Advisory Group

41 The Ministry has been engaging with the Immunisation Implementation Advisory Group (IIAG) for independent, practical advice on how to plan, prepare and implement a COVID-19 immunisation campaign for children 5 to 11 years. The programme will evaluate and plan delivery models with the IIAG to ensure a

paediatric vaccine is delivered in ways that support Māori, Pacific and disabled people to achieve equitable immunisation outcomes.

42 DHBs will be expected to partner with iwi to agree on local rollout plans and priorities for the programme. The COVID-19 Vaccination and Immunisation Programme will facilitate this through their equity teams who are working with service providers to ensure they have the resources they need to target their efforts efficiently.

Implementation progress

43 Most programme delivery elements (logistics, cold chain, supporting technology platforms, available workforce and delivery settings) are already in place. The Ministry of Health is now confirming workforce training requirements, specific operating and handling guidelines to ensure the programme administers the vaccine in line with regulatory and clinical recommendations from 17 January 2022.

44 Our Te Tiriti o Waitangi obligations continue to be an essential element of the planning phase before the rollout commences. Discussions with the Iwi Chairs Forum Pandemic Response Group and CV TAG members have led to a codesign process with Māori. Key elements of the design include a data driven, whanau-based implementation approach with access to a vaccines and health checks, a focus on the celebration of tamariki and their whānau with a back-to-school theme and communications that are developed by Māori for Māori. The Ministry has ongoing engagement with hauora providers on implementation approaches and will utilise lessons learned from the Immunisation Programme to date and by leveraging our partnerships such as with the Iwi Chairs Forum Pandemic Response Group.

45 There will be sufficient vaccine supply and provider capacity available to offer COVID-19 immunisation to all children aged 5 to 11 years concurrently. No sequencing approach is required as was needed in the early part of rollout to adults. However, targeted support and dedicated resource will be important to maximise equitable uptake.

46 The 5- to 11-year-old programme implementation will focus on using the existing infrastructure, service delivery models, vaccinators and channels in a multi-pronged approach from the outset. This will include a broad reach across Aotearoa and a simultaneous, targeted focus on Māori, equity, vulnerable communities, and areas with low vaccination rates.

47 Focused effort will include use of the means that have reached more vulnerable populations and areas well during the 12+ ages COVID-19 immunisation programme – community-based centres, marae, churches, drive-throughs, and pharmacies, etc. These outreach mechanisms will differ by region, local needs and provider plans.

48 The Ministry has been establishing and refining models that reach more vulnerable populations and areas and provide COVID-19 vaccinations at scale. Officials anticipate a certain portion of families in this population cohort will be eager for children to be immunised and will use the existing infrastructure to be immunised shortly after the programme starts.

49 The Ministry will continue to take a multi-pronged approach to co-design this service with our hauora providers to meet the needs of tamariki and their whānau. The Ministry will also work with Te Arawhiti, and Te Puni Kōkiri to strengthen the approach for Tamariki Māori. In some communities, schools and kura may provide a site for immunisation. With rollout starting before schools return for the 2022 school year, any immunisation at or near school sites will be delivered by existing local providers rather than as a separate school-based programme.

50 The Ministry will continue to receive guidance and advice from our Māori experts on the IIAG, CV-TAG, and Tātou Whaikaha Disability Advisory group and other key groups including the New Zealand Māori Council (which has proposed the formation of a group of national Māori organisations to be known as Ngā Mana Whakahaere o COVID-19), Iwi Leaders Forum, and other national Māori organisations. In addition, the Ministry's Immunisation Programme Equity team and Māori Health Directorate will engage with the existing Māori health providers to understand what additional supports and resources may be required to implement this service successfully to tamariki.

51 For disabled children and their whanau, the 5-to 11-year-old programme will continue to promote an inclusive and accessible mainstream first approach, in line with the Enabling Good Lives principles, supplemented with dedicated bespoke approaches. Planning and delivery will take into consideration disabled parents, whānau, āiga, carers and siblings, regardless of whether the child is disabled or not.

52 The Disability plan for 5- to 11-year-olds will maintain the core elements of the existing disability rollout, including:

52.1 Information and communications that are accessible and inclusive, and in a range of formats for families with disabilities, and will be co-designed and co-produced with the disability community

52.2 Local networks will be leveraged to communicate available services, including the Whakarongorau Aotearoa telehealth disability line

52.3 Families, whānau and āiga to have tools and resources to support conversations with disabled children about their healthcare and encouraged to utilise tools like supported decision making practices

52.4 The workforce is well-versed in disability, including disability equity, managing challenging behaviours, supported decision making, and needle phobia

52.5 A range of service delivery options are available, including disability accessible transport, accessible and inclusive mainstream services, pop-up clinics in familiar settings and/or in partnership with disability organisations, low sensory services, allowing for disabled people and their whānau to visit sites prior to immunisation to become familiar with vaccination settings, providing sensory distraction tools, and having food and water available.

53 The Immunisation Programme will be considering how it can increase uptake in communities with lower vaccination rates to ensure Māori, Pacific, and disabled

people achieve equitable outcomes. Advice on how a paediatric programme can be implemented will be provided for the group of Ministers with the power to act over the holiday period.

Broader implications arising from a Paediatric programme

54 Balancing the benefits of immunisation against any consequences for children who are not immunised requires careful consideration. Children should enjoy full access and participation in opportunities and public places.

55 Careful consideration is required around access to information about whether children are immunised, and how that information might be used. The CV TAG and agencies input into the Child Impact Assessment has recommended against that information being available to schools, to reduce the risk of exclusion or conflict. However, officials will provide further advice to the Ministers in 2022 in line with other public health measures.

56 Public settings where children of different age groups mingle will require guidance and likely "workarounds". For example, intermediate schools may have 10- to 13-year-olds in class trips or swimming lessons. Immunisation status should not prevent children being able to participate, and from a child development viewpoint it would be better to not require vaccine certificates from 12- and 13-year-olds than to require them from younger children in a group.

57 I note also that the Ministry of Education is considering how to address the access issue for school children when visiting public spaces as part of their education programmes. Currently this issue is limited to students aged 12 years and over when operators require vaccine certificates from those students.

58 Schools and home education providers are keen for early guidance. Some schools and kura are happy to host immunisation efforts, while others have already been the target of anti-vaccination protests. Finding ways to de-escalate or remove potential conflicts about immunisation of children will be a high priority.

59 I propose that the Ministry of Health reports back to Cabinet in January 2022 on how child wellbeing is best supported when some are immunised and others not, and that this advice includes consideration of:

59.1 Children's access to a wide range of activities and public places during the pandemic

59.2 Access to records of a child's immunisation, including any use of COVID-19 Vaccination Certificates

59.3 Access to International certificates for children who require them for travel

59.4 Guidance and communications resources for education settings

59.5 Guidance for a wide range of government, non-government, community, and business groups on children's access to activities and public places.

Removing the requirement for schools to maintain student vaccine registers

60 On 11 October 2021, Cabinet agreed that education services will be required to maintain an up-to-date register of the vaccine status of eligible secondary school students [CAB-21-MIN-0414 refers].

61 Subsequently, the systems and processes for managing COVID-19 outbreaks have been reworked and the need to collect and use student vaccination status data is no longer essential to those processes.

62 To remove unnecessary workload on schools as soon as possible, the Ministry of Education has advised schools that maintaining a register of the vaccination status of their students is no longer required, although they are able to do so if they choose for their own purposes. The relevant direction under the Education and Training Act 2020 giving legal effect to the requirement has been revoked by the Secretary for Education.

63 I am comfortable that removing this requirement is the right course of action, however, the Ministry's notice to schools, and the Secretary's revocation, has preceded Cabinet approval to make the change. I am now asking Cabinet to note the Secretary's decision.

International considerations

64 New Zealand continues to play a role internationally, supporting access to vaccines particularly for the six countries in Polynesia with whom we have constitutional relationships and/or strong historical and cultural ties: the Cook Islands, Niue, Tokelau, Samoa, Tonga and Tuvalu. New Zealand is also directly supporting access to vaccines in other Pacific countries such as Fiji.

65 Pacific countries have young populations, many of whom are under 12 and therefore ineligible for the Pfizer COVID-19 vaccine for ages 12+. These countries will have a strong interest in vaccinating their 5–11-year-olds in order to strengthen protection against COVID-19 in their populations, especially as the region begins looking towards reconnecting (including with New Zealand and Australia) and the risk of COVID-19 entering their borders increases.

66 New Zealand has received official requests for paediatric vaccines from Cook Islands and Niue, and informal requests from other Polynesian countries. In response, Minister Sio will send letters to the six Polynesian Health Ministers (Cook Islands, Niue, Tokelau, Tuvalu, Samoa and Tonga) to request that our respective officials progress discussions on the countries' interest and consideration of paediatric vaccines.

67 Cabinet has already agreed to continue to support the Cook Islands, Niue and Tokelau to access sufficient vaccines to cover their ongoing immunisation needs in 2022, and to work with other donors to support Samoa, Tonga, Tuvalu and Fiji with their remaining vaccine needs [CAB-21-MIN-0350 refers].

68 New Zealand has procured sufficient volumes of Pfizer's paediatric COVID-19 vaccine to fully immunise those aged 5 to 11 years in Polynesia (130,000 doses).

69 [redacted]

70 The costs relating to the donation of paediatric COVID-19 vaccines to Polynesia will be met within existing baselines, as part of the $75m Pacific and Global Vaccine Access and Roll-out Fund that Cabinet agreed in December 2020 [CAB-20-MIN-0504 refers].

71 I recommend Cabinet agree to donate up to 130,000 doses Pfizer's paediatric vaccine to the six Polynesian countries, in line with New Zealand's Immunisation Programme, and readiness.

Financial Implications

72 There are no financial implications arising from the roll out of the paediatric product.

73 On 15 December 2021, Cabinet vaccination programme as a charge against both the COVID-19 Tagged – Operating Contingency and the COVID-19 Response and Recovery Fund [SWC-21-MIN-0223 refers].

74 The cost of purchasing the paediatric doses has already been confirmed and appropriated for, and will not require additional funding.

Legislative Implications

75 There are no legislative implications arising from the recommendations in this paper.

Population Implications

76 Vaccinating children will increase the proportion of the whole population who have a level of protection from COVID-19, reducing the potential harm COVID-19 could cause in our communities.

77 Tamariki Māori are at higher risk of severe disease and hospitalisation due to COVID-19. Vaccinating children reduces the overall risk in tamariki Māori and risks to their whānau and provides an opportunity to utilise whānau-based approaches to engage with whānau on vaccination (including boosters) and other COVID-19 pandemic support.

78 Pacific children are also at higher risk of severe disease and hospitalisation due to COVID-19. Vaccinating children reduces the overall risk in this population and provides opportunity to engage with aiga on vaccination (including boosters) and other COVID-19 pandemic support.

79 Adults and older persons (65+ ages) are immunised using a different product to the paediatric COVID-19 vaccine. However, other resources such as vaccinators are used by both immunisation programmes. Proposals in this paper such as whānau-based

approaches, engaging family and aiga on vaccine status and booster eligibility outweigh any risk of inequitable resource distribution.

80 Individuals with disabilities are at higher risk of severe disease due to COVID-19. Families with disabilities also have unique needs from public health services and associated messaging. Vaccinating children with disabilities reduces the high level of risk they bear from COVID-19, and proposals in this paper give focus to the needs of families with disabilities who wish to vaccinate their child/children.

Human Rights

81 The proposal in this paper for children aged 5 to 11 years to be offered the vaccine does not engage the right to discrimination on the basis of age, as the right only begins at age 16 (section 21(1)(i) of the Human Rights Act 1993, section 19 of the New Zealand Bill of Rights Act 1990). In any event, this is a rights-positive proposal as it expands access to the vaccines to children aged 5 to 11 years.

Consultation

82 The Ministry of Health has consulted with the Ministry of Foreign Affairs and Trade, Crown Law, Ministry of Education, and the Ministry of Justice. The Department of the Prime Minister and Cabinet has been informed.

Communications

83 The COVID-19 Immunisation Programme communications campaign for 5- to 11-year-olds is underway and will ramp up over the coming months. There are five key phases of the campaign:

83.1 Phase One (underway): General awareness

83.2 Phase Two (17 Dec 2021): Medsafe approval – announcement of the Decision, and further information and education to the Public on the decision-making process.

83.3 Phase Three (20 Dec 2021): Decision to use – announcement of the decision to use, and inform parents and children about rollout timing and how to access vaccination

83.4 Phase Four (17 Jan 2022): Launch – announcement that child vaccination has started nationwide, and detailed information on how to access vaccines for 5- to 11-year-olds

83.5 Phase Five (from 18 Jan 2022): Post launch campaign and mobilisation

84 The purpose of a targeted paediatric vaccination communications strategy is to build trust and confidence in the COVID-19 vaccines and the Immunisation Programme to encourage uptake.

Proactive Release

85 [redacted]

Recommendations

The Minister for COVID-19 response recommends that the Committee:

1 note that New Zealand has purchased sufficient supply of the Pfizer paediatric vaccine for immunisation of the New Zealand population aged 5 to 11 years, and the populations of the six Polynesian countries aged 5 to 11 years.

2 note that Medsafe has granted provisional consent to Pfizer NZ Ltd for distribution of its paediatric vaccine product in New Zealand, for children aged 5 years to 11 years, to be given as two doses at least three weeks apart

3 note that the provisions attached to this approval are similar to those for other COVID-19 vaccine products and relate to ongoing provision of information regarding storage, quality assurance and safety

4 [redacted]

5 note that the COVID-19 Vaccine Technical Advisory Group (CV TAG) has recommended that:

5.1 that Pfizer paediatric vaccine be offered to all children aged 5 to 11 years, to be given as two doses eight weeks apart or at least three weeks apart where there is good reason for a shorter dose interval

5.2 mandates, vaccine certificates or vaccine targets must not be used for this age group and children should not be denied access to locations or events or excluded based on their vaccination status

5.3 focus be given to immunisation of Māori and Pacific children, children with high-risk pre-existing conditions and children living with vulnerable people

5.4 focus also be given to improving access and uptake of COVID-19 vaccination and boosters in adults, other childhood immunisation in children, and strengthening public health measures in schools and other education settings

5.5 careful safety monitoring be undertaken with recommendations reviewed as data emerges from the US and Canadian immunisation programmes for children

6 note that the Ministry of Health has completed a child wellbeing impact assessment and its findings are consistent with the CV TAG advice, including that:

6.1 immunisation of the wider population is important to protect children and promote their wellbeing

6.2 immunisation of children adds protection and promotes children's development with or without high levels of population immunisation

6.3 immunisation of tamariki Māori requires high and urgent focus; Māori have suffered high pandemic impacts, remain at high risk, and have a younger child population with 10% of Maori under 5 years old who are ineligible for vaccine

6.4 immunisation of children should be voluntary with no associated restrictions for any children

6.5 immunisation of children should where possible promote whānau wellbeing

7 agree to use the Pfizer paediatric vaccine for immunisation of children aged 5 to 11 years in accordance with CV TAG advice where doses are to be given as two doses eight weeks apart or at least three weeks apart where there is good reason for a shorter dose interval

8 agree that, to promote children's wellbeing:

8.1 high priority be given to engagement with and resourcing for Māori to promote COVID-19 immunisation uptake for children and adults, together with access and uptake other health and social measures that promote whanau wellbeing and the wellbeing of tamariki Māori

8.2 high priority be given to promotion of immunisation for children who are, like tamariki Māori, at higher risk of exposure to and impacts from COVID-19, including Pacific children, children with disabilities and health conditions and children in the care of Oranga Tamariki

9 note that, if you agree, immunisation rollout for children aged 5 to 11 years is being planned to start from 17 January 2022

10 note that Cabinet is not scheduled to meet until 21 January 2022, and implementation decisions may potentially be required over the shutdown period

11 agree that the group of Ministers (Prime Minister, the Minister of Finance, the Minister for COVID-19 Response, and the Minister of Health) have the power to act to ensure timely decision making on implementation of the COVID-19 Immunisation Programme should this be required during the parliamentary break

12 note that officials will report back to the group of Ministers with power to act over the holiday period on the implementation approach prior to opening up invitations for children aged 5 to 11 years, this will reflect lessons learned in the initial phase of the vaccination programme and an update on the ongoing co-design process currently underway with hauora providers and iwi representatives

13 note that the Ministry of Health will report back to Cabinet during January 2022 on children's access to a wide range of activities and public places during the pandemic

and on any disclosure or use of immunisation records, certificates, or passports for children

14 note that the Secretary for Education has removed the requirement for secondary schools to maintain registers of students' vaccination status, as this is no longer required to support contact tracing and management of potential outbreaks.

15 agree to donate up to 130,000 doses of Pfizer's paediatric vaccine to the six Polynesian countries, in line with New Zealand's Immunisation Programme

16 [redacted]

Authorised for lodgement

Hon Chris Hipkins

Minister for COVID-19 Response

CAB-21-MIN-0557

Cabinet

Minute of Decision

COVID-19 Pfizer Vaccine for Children Aged 5 to 11 Years: Decision to Use

Portfolio **COVID-19 Response**

On 20 December 2021, Cabinet:

1 **noted** that New Zealand has purchased sufficient supply of the Pfizer paediatric vaccine for immunisation of the New Zealand population aged 5 to 11 years, and for the populations of the six Polynesian countries aged 5 to 11 years;

2 **noted** that Medsafe has granted provisional consent to Pfizer NZ Ltd for the distribution of its paediatric vaccine product in New Zealand, for children aged 5 years to 11 years, to be given as two doses at least three weeks apart;

3 **noted** that the provisions attached to this approval are similar to those for other COVID-19 vaccine products and relate to the ongoing provision of information regarding storage, quality assurance and safety;

4 [redacted]

5 **noted** that the COVID-19 Vaccine Technical Advisory Group (CV TAG) has recommended that:

5.1 the Pfizer paediatric vaccine be offered to all children aged 5 to 11 years, to be given as two doses eight weeks apart or at least three weeks apart where there is good reason for a shorter dose interval;

5.2 mandates, vaccine certificates or vaccine targets must not be used for this age group, and that children should not be denied access to locations or events or be excluded based on their vaccination status;

5.3 focus be given to the immunisation of Māori and Pacific children, children with high-risk pre-existing conditions, and children living with vulnerable people;

5.4 focus also be given to improving access and uptake of COVID-19 vaccination and boosters in adults, other childhood immunisation in children, and strengthening public health measures in schools and other education settings;

5.5 careful safety monitoring be undertaken, with recommendations reviewed as data emerges from the United States and Canadian immunisation programmes for children;

6 **noted** that the Ministry of Health has completed a child wellbeing impact assessment, and that its findings are consistent with the CV TAG advice, including that:

6.1 immunisation of the wider population is important to protect children and promote their wellbeing;

6.2 immunisation of children adds protection and promotes children's development with or without high levels of population immunisation;

6.3 immunisation of tamariki Māori requires high and urgent focus – Māori have suffered high pandemic impacts, remain at high risk, and have a younger child population with 10 percent of Maori under 5 years old who are ineligible for vaccine;

6.4 immunisation of children should be voluntary, with no associated restrictions for any children;

6.5 immunisation of children should, where possible, promote whānau wellbeing;

7 **agreed** to use the Pfizer paediatric vaccine for immunisation of children aged 5 to 11 years in accordance with CV TAG advice where doses are to be given as two doses eight weeks apart or at least three weeks apart where there is good reason for a shorter dose interval;

8 **agreed** that, to promote children's wellbeing:

8.1 high priority be given to engagement with and resourcing for Māori to promote COVID-19 immunisation uptake for children and adults, together with access and uptake of other health and social measures that promote whanau wellbeing and the wellbeing of tamariki Māori;

8.2 high priority be given to the promotion of immunisation for children who are, like tamariki Māori, at higher risk of exposure to and impacts from COVID-19, including Pacific children, children with disabilities and health conditions, and children in the care of Oranga Tamariki;

9 **noted** that immunisation rollout for children aged 5 to 11 years is being planned to start from 17 January 2022;

10 **noted** that Cabinet is not scheduled to meet until 25 January 2022, and that implementation decisions may potentially be required over the shutdown period;

11 **authorised** the COVID-19 Ministerial Group [CAB-21-MIN-0353] to have the power to act to ensure timely decision making on the implementation of the COVID-19 Immunisation Programme should this be required during the parliamentary break;

12 **noted** that:

12.1 officials will report back to the group of Ministers with power to act over the holiday period on the implementation approach prior to opening up invitations for children aged 5 to 11 years;

12.2 this will reflect the lessons learned in the initial phase of the vaccination programme and an update on the ongoing co-design process currently underway with hauora providers and iwi representatives;

13 **noted** that the Ministry of Health will report back to Cabinet during January 2022 on children's access to a wide range of activities and public places during the pandemic, and on any disclosure or use of immunisation records, certificates, or passports for children;

14 **noted** that the Secretary for Education has removed the requirement for secondary schools to maintain registers of students' vaccination status, as this is no longer required to support contact tracing and management of potential outbreaks;

15 **agreed** to donate up to 130,000 doses of Pfizer's paediatric vaccine to the six Polynesian countries, in line with New Zealand's Immunisation Programme;

16 [redacted]

Michael Webster
Secretary of the Cabinet

This is the exhibit marked "**ARB-17**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

Memo

Use of the paediatric Pfizer COVID-19 vaccine in 5-11 year-olds – second dose and dosing interval: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	16 February 2022
To:	Dr Ashley Bloomfield, Director-General of Health
Copy to:	[redacted]
From:	Dr Ian Town, Chief Science Advisor
For your:	Consideration

Purpose of report

1. To outline the COVID-19 Vaccine Technical Advisory Group's (CV TAG) advice about the administration of a second dose of the paediatric Pfizer vaccine and the interval between the first and second doses of the COVID-19 vaccine for 5–11 year-olds.
2. This report also provides an update on international and local safety data.

Background and context

3. Vaccination of 5–11-year-olds in New Zealand is now underway. The approved COVID-19 paediatric Pfizer vaccine being used has a lower dose (10 µg) and a smaller volume (0.2 mL) than the adult vaccine and is administered using a smaller needle. As at 13 February 2022, 214,857 (45%) of 5–11-year-olds had received their first dose in New Zealand. [1] Only 26% of Māori 5-11 year-olds and 36% of Pacific 5-11 year-olds have received their first dose. To be fully immunised against COVID-19, a child needs to receive two doses of the paediatric vaccine.
4. In December 2021, CV TAG recommended that two doses of the paediatric Pfizer vaccine be offered to all 5-11 year-olds in Aotearoa New Zealand, with an 8-week interval between doses (Appendix 1, *Decision to Use the Pfizer mRNA COVID-19 vaccine for children aged 5-11 years: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations*). It was also indicated that in February 2022, CV TAG would assess the latest data and provide updated recommendations prior to any second doses being given to this age group in New Zealand.

Safety data for the Pfizer vaccine in 5–11-year-olds

5. A randomised clinical trial to assess the safety, immunogenicity, and efficacy of the Pfizer vaccine in 5-11 year-olds of two doses administered three weeks apart reported more local reactions and systemic events than placebo recipients. [2] The reactions and events reported were generally mild to moderate, lasting 1 to 2 days. Injection-site pain was the most common local reaction, occurring in 71 to 74% of Pfizer recipients. Severe injection-site pain after the first or second dose was reported in 0.6% of Pfizer recipients and in no placebo recipients.

6. In the clinical trial, fatigue and headache were the most frequently reported systemic events (0.9%), headache (0.3%), chills (0.1%), and muscle pain (0.1%) were also reported after the first or second dose of Pfizer. [2] Frequencies of fatigue, headache, and chills were similar among Pfizer and placebo recipients after the first dose and were more frequent among Pfizer recipients than among placebo recipients after the second dose.

7. No vaccine-related serious adverse events were noted in the clinical trial; however, the trial was too small to detect rare side effects such as myocarditis. [2] Three serious adverse events were reported from two participants (postinjury abdominal pain and pancreatitis in a placebo recipient and arm fracture in a Pfizer recipient), however, none of these were related to the vaccine or placebo. No deaths or adverse events leading to withdrawal were reported. There were no cases of severe COVID-19 or Multisystem Inflammatory Syndrome in Children (MIS-C)—a condition associated with COVID-19 where body parts can become inflamed. Lymphadenopathy was reported in ten Pfizer recipients (0.9%) and one placebo recipient (0.1%). No myocarditis, pericarditis, hypersensitivity, or anaphylaxis in Pfizer recipients was reported. Rashes in four Pfizer recipients (observed on the arm, torso, face, or body, with no consistent pattern) were related to vaccination; the rashes were mild and self-limiting, and onset was typically 7 days or more after vaccination.

8. Real-world safety data has been collected from over 8 million doses of the Pfizer vaccine administered to children aged 5–11 years in the United States. These data have been collected in the Vaccine Adverse Event Reporting System (VAERS), a national passive vaccine safety surveillance system, and through V-safe, a voluntary smartphone-based safety surveillance system for adverse events after COVID-19 vaccination. [3] From November 3 to December 19, 2021, VAERS received and processed 4,249 reports of adverse events for children aged 5–11 years who received Pfizer COVID-19 vaccine. Overall, among VAERS reports for children aged 5–11 years who received the Pfizer vaccine, approximately 97% were non-serious. The most commonly reported conditions among the 100 reports of serious events were fever (29.0%), vomiting (21.0%), and increased troponin (15.0%). Among 12 serious reports of seizure, five children experienced new-onset seizures. Among 15 preliminary reports of myocarditis identified during the analytic period, 11 met the case definition for myocarditis. VAERS received two reports of death both of whom had complicated medical histories and were in fragile health before vaccination. None of the data suggested a causal association between death and vaccination. In V-safe, fever was found to be more frequently reported in 5-11 year-olds after dose 2 (4,001: 13.4%) than dose 1 (3,350; 7.9%) among 42,504 recipients of dose 1 and 29,899 recipients of dose 2. Overall, systemic reactions after dose 2 among registrants aged 5-11 years were less frequent than among children aged 12-15 years. Fourteen registrants aged 5–11 years received hospital care after vaccination. Information regarding reason for hospitalisation was available for five children

and included appendicitis (two), vomiting and dehydration (one), respiratory infection (one), and retropharyngeal cellulitis (one).

Reporting of Adverse Events following Vaccination in New Zealand

9. In New Zealand, preliminary unpublished data from Medsafe indicates that there have been 352 adverse events following immunisation (AEFIs) reported from 17 January to 30 January 2022 in children aged 5-11 who received the approved COVID-19 paediatric Pfizer vaccine. Of these, 96.9% (341) reports were classified as non-serious. A small number of individuals (10) reported that an AEFI required emergency care and one AEFI case was admitted to hospital for observation (no evidence of myocarditis despite reporting chest discomfort). Of these 11 cases, six were reported as recovered or recovering, one was ongoing, and four had an unknown outcome. Chest discomfort was the most frequently reported reaction (6), followed by vasovagal reaction (4), and there was one case of anaphylaxis (Brighton criteria level 4).
10. Medsafe is in regular contact with other regulators and have noted that to date nothing of concern has been drawn to their attention regarding the safety profile of the paediatric Pfizer vaccine.

Rationale for an 8-week interval

11. The manufacturer's recommended schedule for the paediatric Pfizer vaccine is 2 doses, 3 weeks apart.
12. Research conducted in adults into extending the dosing interval (e.g., to 8 weeks or longer) has shown that longer intervals between the first and second Pfizer dose can lead to higher humoral and cellular immune responses, improved vaccine effectiveness, and potentially a longer duration of protection compared with the standard interval. [4-7] In addition, data from adults show that an extended dosing interval may also reduce the risk of myocarditis and pericarditis after vaccination. [8]
13. Extended dosing intervals has not yet been studied in children, but it is expected that similar effects would be observed to those after extended dosing intervals in adults, such as improved immunogenicity and the potential for a lower risk of serious side effects. The recommendation for an 8-week interval between doses is consistent with other international advisory groups, such as in the UK, Canada, and Australia. [9-11] In addition, a longer interval between doses would allow more time to continue monitoring international safety data as it emerges.

Priority groups for children aged 5-11 years

14. Māori and Pacific children have been disproportionately affected in this pandemic. For community-acquired cases up to 11 February 2022, Māori made up 45.7% of total cases in 5- to 11-year-olds, and Pacific children have made up 28.7% of cases among 5- to 11-year-olds. Of these cases, a total of ten have been hospitalised, with Māori and Pacific children combined making up 90% of these cases. As noted above, in the vaccine rollout for 5–11-year-olds, fewer Māori and Pacific children have been vaccinated than other ethnicities. Prioritisation of Māori and Pacific children remains important, and the emphasis should be to get the first dose administered to as many as children as possible.

15. Children living with pre-existing conditions or comorbidities, from disadvantaged backgrounds, or those living within a lower socioeconomic status have a greater risk of severe disease from COVID-19. [12-16]

16. Starship Child Health has listed risk factors for COVID-19 disease [17] that may be used as guidance for prioritising children with high-risk pre-existing conditions. The current list of risk factors includes children with:
    - Chronic lung disease including bronchiectasis, cystic fibrosis, BiPAP for OSA
    - Non-repaired congenital heart disease, acquired heart disease or congestive heart failure
    - Poorly controlled asthma (regular symptoms occurring in a usual week that affect the patient's quality of life and includes anyone with an admission in the last 2 years or anyone with 2 or more courses of steroids in the last two years)
    - Obesity (BMI ≥95th centile for age)
    - Diabetes (insulin-dependent)
    - Chronic kidney disease (GFR <15 ml/min/1.73m^2)
    - Severe cerebral palsy (or neurodevelopmental disorder)
    - Complex genetic, metabolic disease or multiple congenital anomalies.

17. Children in other recognised clinical risk groups who are at higher risk of severe COVID-19 should also include those who are a household contact of someone who is immunosuppressed (defined as those who expect to share living accommodation on most days (and therefore for whom continuing close contact is unavoidable) with individuals of any age who are immunosuppressed).

Recommendations

18. CV TAG met on 1, 8, and 15 February 2022 to consider guidance on administering a second dose of the vaccine and the interval between doses for 5–11-year-olds.

19. CV TAG noted:

    a. **The direct and indirect impacts on children.** Children who have COVID-19 will commonly have few or only mild respiratory symptoms. COVID-19 in this age group is rarely severe or fatal, [18, 19] and the rate of severe COVID-19 disease in this age group is the lowest of any age group. However, there is a very small but real risk of MIS-C (described above) at this age which has occurred more frequently among ethnic minorities in the US. [12, 20] A very small proportion of children also experience persistent illness and ongoing symptoms, though evidence about its incidence is limited.

    b. Children living with pre-existing conditions or comorbidities, from disadvantaged backgrounds, or those living within a lower socioeconomic status have a greater risk of severe disease from COVID-19. [12-15]

    c. Even though the direct effects of infection are generally less severe in children, this should not diminish the significance for those who have experienced worse outcomes. [19] Alongside the direct risks and impacts to health and individuals, COVID-19 also has indirect impacts for children on mental health, wellbeing, education and social development, and these are worsened by lockdowns and school closures. [12, 21-23]

    d. **Children do play a role in transmission however it is significantly smaller than for adults**. Transmission within education settings has occurred but is limited and is more

likely to occur between adults. [24-26] Transmission in households is much more common. [27, 28] The benefit of vaccination on onward transmission in households could be lower than in other settings due to the ongoing and close nature of exposure. [29, 30] but this is not confirmed. The effect of vaccination of children on household transmission is unknown.

e. **There are a number of equity considerations which are important to consider**:

   i. Māori and Pacific children have been disproportionately affected in the current outbreak. To 11 February 2022, Māori made up 45.7% of cases in 5-11 year-olds, and Pacific children have made up 28.7% of cases among 5-11 year-olds.

   ii. Māori and Pacific adults are at greater risk of COVID-19 hospitalisation and severe disease. Māori and Pacific adults have respectively 2.5-fold and 3-fold higher odds of being hospitalised compared to non-Māori, and Māori are likely to spend 4.9 days longer in hospital. [31, 32]

   iii. Māori and Pacific children are more likely to live in multigenerational families housed in overcrowded conditions, increasing the risk of transmission. The younger age structure of the Māori population also means that a larger proportion are currently unable to be vaccinated and remain susceptible to infection and transmission, with a risk of onwards transmission to whānau and communities, [33, 34] though the risk of transmission from children is lower than from adults.

f. **The paediatric formulation of the vaccine has been approved for emergency use and rolled out in the USA, Canada, and Israel**. The Advisory Committee on Immunization Practices (ACIP) made an interim recommendation for the emergency use of the Pfizer vaccine in children aged 5-11 years in the United States for prevention of COVID-19. [19, 35] This was unanimously supported by the Committee. In making this recommendation, ACIP considered the importance of COVID-19 as a public health problem, as well as benefits and harms, parents' values and preferences, acceptability, feasibility, resource use, and equity for use of the vaccine among children. [19, 35] ACIP additionally stated: "children from racial and ethnic minority groups have experienced a disproportionately high incidence of COVID-19 as well as secondary impacts of the COVID-19 pandemic such as reduced in-person learning". [19] These comments have high relevance for New Zealand given the similar effects of the pandemic on Māori and Pacific Peoples as described above.

g. **In Australia, the Therapeutic Goods Administration (TGA)** provisionally approved the Pfizer vaccine as safe and effective for use among this age group on 5 December 2021. [36] ATAGI recommends all 5–11-year-olds be vaccinated with an 8-week interval between doses, and that those at risk of severe disease, Aboriginal and Torres Strait Islanders, and children in crowded conditions or outbreak areas be prioritised. [37]

h. **On dosing intervals,** there are no data available about extending the interval between doses of the paediatric formulation of the Pfizer vaccine, however, emerging data in adults suggests that the immune response is likely improved by extending the dosing interval. [4-7] This is consistent with basic principles of vaccinology and immunology which suggests that immune responses are generally better with longer intervals. There may also be a connection between shorter intervals and increased reactogenicity or adverse events, and one pre-print paper on individuals aged 12 and over has shown

a statistically significant increase in myocarditis if the second dose was given at a shorter interval of less than 30 days. [8] Australia, Canada, and the UK have recommended an 8-week interval between doses for 5-11 year-olds, noting this may improve immunogenicity and reduce side effects. Having a longer interval would also allow more time to monitor international safety data.

i. **On vaccine requirements,** there is a significant risk that use of vaccination mandates or certificates in this age group will result in exclusion and an inability to fully participate in schooling and extracurricular activities. This is likely to inequitably impact communities who are already experiencing disadvantage and where current vaccine coverage is poor. Concerns regarding possible stigmatisation and exclusions could be addressed in ways that do not necessarily influence the decision to use. For example, there could be a policy decision that children cannot be denied access to locations/events on the basis of vaccination status, which could be operationalised by not issuing vaccine certificates for this age group.

j. **On safety of the paediatric vaccine,** real-world data on the rollout of the vaccine to 5–11-year-olds have reported nothing of concern to date.

20. **CV TAG recommended that:**

    a. A second dose of the paediatric Pfizer vaccine be offered to all 5–11 year-olds in Aotearoa New Zealand, with a minimum 8-week interval between doses.

    b. Māori and Pacific children, children with high-risk pre-existing conditions, and children living with vulnerable people should continue to be prioritised for vaccination.

21. CV TAG will continue to monitor all relevant information (including safety data) and will update their recommendations as information becomes available.

Dr Ian Town
Chief Science Advisor and
Chair of the COVID-19 Vaccine Technical Advisory Group

Noted
16/2/22

"ARB-18"

This is the exhibit marked "**ARB-18**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

Memo

COVID-19 paediatric vaccine use for children 5 to 11 years

Date:	15 December 2021
To:	Vaccine Ministers
From:	Maree Roberts, Deputy Director-General, System Strategy and Policy
For your:	Noting

Purpose of report

1. This memo informs you of progress in considering use of Pfizer's paediatric COVID-19 vaccine and advises on key points highlighted by a child wellbeing impact assessment and implications for immunisation rollout under the COVID-19 Protection Framework.

Background and context

COVID-19 immunisation in New Zealand

2. COVID-19 immunisation provides the most significant personal protection against illness from COVID-19 and especially against severe illness and long-lasting impacts. Close to 90% of the eligible population in New Zealand (76.5% of the total population) are now fully immunised. Vaccination coverage is increasing yet remains inequitably distributed.

3. In the current New Zealand outbreak, the majority of cases have been in unvaccinated (64%) or partially vaccinated (20%) people[i]. Similarly, most of those hospitalised have been unvaccinated (72%) or partially vaccinated (21%). This is despite unvaccinated people currently making up just 23.5% of the total population.

4. Over the full course of the pandemic in New Zealand, Māori (17.1% of the New Zealand population) have been significantly over-represented in cases (36%), hospitalisations (38%) and deaths (30%)[i]. Pacific peoples (8.2% of the New Zealand population) have also been over-represented in cases (29%), hospitalisations (36%) and deaths (24%).

5. Children and young people are over-represented in cases (37% under 20 years including 20% under 10 years). At the time of infection, most of these children and young people would have been ineligible or newly eligible for vaccination and, currently, those aged under 12 years (15% of New Zealand's population) remain ineligible.

6. While children and young people most often have mild if any symptoms of COVID-19, 10% of New Zealand's hospitalised cases have been in those aged under 20 years.

[i] Case data are as provided on the Ministry of Health COVID-19 case demographics web page as at 12 December 2021 https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-case-demographics#vaccinations-details

Paediatric COVID-19 vaccine and impact on immunisation coverage

7. Medsafe is considering an application by Pfizer for its paediatric vaccine to be approved for use in 5 to 11 year olds. Medsafe expects to make a decision on this application at the end of this week. The COVID-19 Vaccine Technical Advisory Group (CV-TAG) is developing advice on use of Pfizer paediatric vaccine in New Zealand. If Medsafe approves use of the vaccine, CV-TAG will finalise its advice shortly afterwards.

8. The availability of a paediatric vaccine for children aged 5 to 11 years would leave only those under 5 years of age (6% of the total population including 10% of Māori and 8% of Pacific peoples) not eligible for COVID-19 vaccination.

9. With the new larger eligible population, achieving 90% coverage would mean that 84% of New Zealanders have personal protection against COVID-19. Only a handful of countries (Chile, China, Cuba, Portugal and the United Arab Emirates) are reported to have reached this level of population coverage to date.

10. However, equitable immunisation coverage across whole communities would require 100% vaccination of eligible Māori (as 10% of Māori are aged under 5 years), and over 98% of eligible Pacific peoples (as 8% of Pacific peoples are under 5 years).

Child wellbeing impact assessment

11. The Ministry is completing an assessment of the impacts on child wellbeing of COVID-19 immunisation for children 5 to 11 years old. This will inform decisions on use of the COVID-19 paediatric vaccine for this age group, subject to Medsafe approval and CV-TAG advice. A draft of the assessment report is attached.

Key points

12. The draft impact assessment has highlighted that:

Immunisation of the population protects children and promotes their wellbeing

a. COVID-19 has had, and will continue to have, significant impacts on children's health, education and development, relationships and lives; both COVID-19 and measures taken to mitigate the impacts of COVID-19 (for example restrictions on in-person learning) impact significantly on children's lives and development.

b. Immunisation of our wider population against COVID-19 is the most significant protection against the impacts on children's lives and development.

Immunisation of children adds protection and promotes children's development

c. With or without high levels of population immunisation, immunisation of children (subject to Medsafe approval of the vaccine and CV-TAG advice to assure safety, quality and effectiveness) adds additional protection against the impacts on children's lives and promotes their development.

d. Tamariki Māori, Pacific children, children with disabilities and health conditions, children living in poverty and children in the care of Oranga Tamariki are at higher risk of exposure to COVID-19. Disruption due to COVID-19 mitigation is also likely to have higher impacts on these groups. Immunisation adds additional protection for these groups and strongly promotes their development.

Vaccination of tamariki Māori is a high priority

e. Given higher risk factors for Māori and the very young population structure with 10% of Māori under 5 years, vaccination of tamariki Māori is a high priority. Vaccination through whānau-centred approaches, designed to encourage iwi, hapū and Māori in a variety of settings, can promote vaccination of Māori whānau alongside tamariki, and should be given urgent priority and resource.

Vaccination of children should be voluntary with no associated restrictions for any children

f. Promotion of children's development via immunisation is optimised where vaccination of children is voluntary, parents and guardians are active participants in the decision for their children to be vaccinated, and children themselves are engaged in the process as appropriate for their age and development.

g. Promotion of children's development via immunisation would be undermined and potentially worsened overall by any restrictions, mandates or certification requirements, or other measures that single out children based on whether or not they are vaccinated.

Vaccination of children should, where possible, promote whānau wellbeing

h. Promotion of children's development via immunisation would be enhanced by delivering vaccines in whānau-centred ways that offer a range of health and social development opportunities and services, without undue delay. Examples include whānau health checks, concomitant immunisation of whānau members with COVID-19 and other vaccines, and promotion of a range of housing, social, financial and legal assistance where possible.

Consistency with WHO guidance

13. WHO issued an Interim statement on COVID-19 vaccination for children and adolescents (updated 29 November 2021)[ii]. It states that:

    a. Countries should consider the individual and population benefits of immunising children in their specific epidemiological and social context

    b. Benefits go beyond direct health benefits – minimising disruptions to education and maintenance of overall well-being, health and safety are important

    c. Attaining high coverage of high-risk groups such as older people, those with chronic health conditions and health workers, including booster doses, should be prioritised before children and adolescents

    d. Global sharing through the COVAX facility should be prioritised before vaccination of children and adolescents who are at low risk for severe disease.

14. The child wellbeing impact assessment is being informed by this WHO guidance.

Balancing the benefits of COVID-19 vaccination for children aged 5 to 11 years old

15. Compared to adults, children have a lower risk of serious illness from COVID-19. While most children appear to have mild symptoms, the potential risk of transmission to immunocompromised children, adults and vulnerable family or community members

[ii] https://www.who.int/news/item/24-11-2021-interim-statement-on-covid-19-vaccination-for-children-and-adolescents

16. Internationally, many recent large COVID-19 clusters have been centred in schools, including primary schools (for example in the UK and Australia).

17. Balancing the benefits of vaccination against any consequences for those who are not vaccinated requires careful consideration, including having regard to access to the vaccination status of a child and how that information may potentially be used. Knowledge of the vaccination status could inadvertently lead to exclusion either informally (e.g. bullying) or formally (e.g. school activities, sporting, education, and social settings).

18. Parental consent/non-consent should also not create indirect consequences for children, that could lead to potential exclusion from developmentally important social and education activities.

19. Without careful consideration of some of these issues, there is the risk of increasing equity gaps for children (whether directly or indirectly), when we know these gaps are disproportionately harmful for children compared with adults.

Requiring COVID-19 vaccination and vaccine passes for children aged 5 to 11 years old

20. Drawing on the Child Wellbeing Impact Assessment, and with the currently limited scientific evidence, the Ministry's position is that vaccination of this age group should remain voluntary (particularly in the context of vaccine passes or for confirmation of vaccination status).

21. Schools in New Zealand already gather general vaccination data from all students at enrolment. High schools are requesting COVID-19 vaccination data from students to help them plan and manage any potential outbreaks. Primary schools are likely to request this information also, once children aged 5 to 11 years are being vaccinated.

22. As children cannot be excluded from education settings based on their vaccination status (right to education), and given the school records already being kept, vaccine passes would not be needed or appropriate in school settings. Further guidance may be required for children visiting public settings that require vaccine passes as part of school activities with different age groups together (under 12s and over 12s.)

23. Outside of schooling, children in the 5-11 years age group are likely to be accompanied by vaccine pass carrying adults when entering premises that require vaccine passes. There is little to indicate that children in this age group should require a vaccine pass.

24. Overseas examples of vaccine passes being required for 5 –11-year-olds are limited as COVID-19 vaccination programmes for younger age groups have only recently started. In the UK there are slightly different settings for Scotland, Wales and England, but generally vaccine passes are not required for anyone under the age of 18 years. Denmark does not require vaccine passes for anyone under the age of 16 years. New York City however, will be introducing passes for 5 –11-year-olds in line with other age groups and Israel requires vaccine passes to be used by all, with only children under 3 being exempt.

25. With the evolving nature of the pandemic and new COVID-19 variants emerging, this situation may change. At this stage as it is too early to find clear evidence demonstrating that children aged 5-11 years should be required to be vaccinated against COVID-19 and therefore be required to carry a vaccine pass.

26. The Ministry's current view is the decision by caregivers to vaccinate their children should remain voluntary with no associated restrictions for any children under the COVID-19 Protection Framework.

Preparing for implementation

27. Planning is well underway for the vaccination rollout so there will be minimal delay once decisions have been made, most likely over the Christmas/New Year holiday period, on offering the paediatric vaccine. This work includes the following:

    a. The Immunisation Advisory Centre (IMAC) are developing training modules and resources for use of the paediatric vaccine that can be finalised for workforce groups from early in the New Year. Additional training will be strongly recommended.

    b. Logistics and facilities for vaccine storage and distribution are well advanced.

    c. Suitability for children is being assessed and guidance developed across the range of different vaccination delivery models. For example, drive-through vaccination suits some families including many Pacific families; additional guidance on observation and surrounding facilities and staffing is being developed, and dry runs and trial runs will be needed to adapt.

    d. DHBs and providers have gained experience across a wide range of community-friendly vaccination delivery models with adaptations for particular communities and localities. Most of these models are likely to be used in the paediatric vaccine rollout.

    e. Engagement with Hauora Māori and Pacific providers and family and community groups will facilitate promotion and acceptability of paediatric immunisation models.

    f. Some communities are only now getting to high uptake among younger adults who are likely to be well-represented in parent groups for 5 to 11 year olds. While this may provide good opportunities for whole whānau vaccination and other health and social services, there is likely to be some delay in higher vaccination uptake for children in these communities.

    g. Schools and home education providers are keen for early guidance. Some are happy to host vaccination efforts, others have already been the target of anti-vaccination protests. Finding ways to de-escalate or remove potential conflicts over vaccination of children will be a high priority.

    h. No certification is being offered at this stage.

Next steps

28. The Ministry is preparing advice for delegated Ministers to support decisions on whether to use the Pfizer paediatric vaccine for children aged 5-11 years in New Zealand.

29. That advice will include further details on the advice from Medsafe and CV TAG as well as more details on the planning for the roll out of delivery of COVID-19 vaccines for children in this age group.

30. Cabinet is considering its delegations for these decisions this week.

Signature [redacted] Date: 15/12/21

Maree Roberts
Deputy Director-General, System Strategy and Policy

"ARB-19"

MINISTRY OF HEALTH
MANATŪ HAUORA

This is the exhibit marked "**ARB-19**" referred to in the annexed Affidavit of **ASHLEY ROBIN BLOOMFIELD** affirmed at **Wellington** this 13 day of **June 2022** before me:

Solicitor of the High Court of New Zealand

133 Molesworth Street
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15 December 2021

Tēnā koe

Urgent update on COVID-19 Vaccine-associated Myocarditis and Pericarditis

In response to recent reports of myocarditis/pericarditis following vaccination with Pfizer Comirnaty vaccine, the COVID-19 Vaccine Immunisation Programme (the Programme) is working to strengthen our system-level approach to ensure the best possible outcomes for our population should they experience this adverse event. This letter is to request you to support us by leading a response in your region, in partnership with primary care, urgent care, pharmacy, and other community organisations and providers. We need to ensure that consumers are well informed of this rare side effect and know when to seek help. We also want to ensure that the health system is poised to diagnose and clinically manage consumers with this condition appropriately.

Myocarditis and pericarditis have been established as very rare but serious adverse events associated with the Comirnaty vaccine. Although people with these conditions are usually diagnosed, investigated and managed effectively within our health system, the Programme's vaccination safety surveillance analysis, conducted in conjunction with Medsafe, highlights the need to reiterate the importance of timely assessment and management to prevent the serious consequences of myocarditis/pericarditis.

In New Zealand, the true incidence of vaccine-associated myocarditis is unknown as the onset of symptoms occurs in the first few days after vaccination and is potentially under-reported. However, the overall rate of this event in New Zealand is reported to be around 3 per 100,000 vaccinations.

The international literature is helpful in identifying the demographic and clinical characteristics of those who are more likely to have this adverse event. However, the pattern of the reports to the Centre for Adverse Reactions Monitoring (CARM) in New Zealand is slightly different. Our data shows that clinically-validated myocarditis/pericarditis in the 30-days following the vaccine occurs:

- Approximately equally in both males and females
- Over a wide age range, with a median age of diagnosed cases in the mid-30s
- Approximately equally after dose 1 and after dose 2[1].

In this New Zealand data, the most common symptomatology described is:

- Chest heaviness, discomfort, tightness or pain
- Difficulty breathing, shortness of breath
- Feeling dizzy, light-headed or faint
- Racing or fluttering heart, or a feeling of 'skipped beats'

The onset of these symptoms was usually in the first few days following the vaccine but can occur in the weeks later.

Serious complications of this condition are avoidable with timely assessment and treatment. A critical component to preventing the harm of vaccine-associated myocarditis/pericarditis is effective person-centred communication at point of vaccination. We know vaccinators and clinicians are

[1] We do not yet have sufficient data in New Zealand around occurrence after boosters.

excellent in describing the common and mild vaccine side-effects to consumers prior to vaccination as part of the consent conversation. However, informing consumers of the rare and serious potential side-effects (such as anaphylaxis, myocarditis and pericarditis) is also crucial. The few people who will be affected by vaccine-associated myocarditis/pericarditis must know what symptoms they might experience, and when and how to seek medical advice in time to prevent harm. This is important information also for those who present with parents and caregivers.

What we are doing as part of our response

- We are working with Whakarongorau Aotearoa to update the 0800 Helpline screening questions and advice.
- There are several changes underway to strengthen consumer knowledge on the symptoms of myocarditis/pericarditis in the range of vaccination information sheets including when and how to seek help. All website content on this issue will also be reviewed and updated.
- IMAC's webinar on vaccine-associated risks is available now and will be revised to strengthen key messages on myocarditis/pericarditis.
- Safety monitoring of the vaccine continues including active monitoring for some consumers via text message. The health sector will be updated on actions to prevent the serious consequences of untreated or misdiagnosed myocarditis as required.
- The effectiveness of the changes and approach will be evaluated in late January.
- Communication with key stakeholder groups to facilitate them to activate their networks and update their resource material with this information.

What can you do?

- Engage local leadership to work with your Programme and site Clinical and Quality leads to ensure all vaccinators in your region have up-to-date clinical knowledge and have reviewed the resources available on vaccine-associated myocarditis/pericarditis.
- The vaccinating workforce are required to review the IMAC webinar as soon as practical, and ensure they are competent and confident to provide consumers with information on the symptoms of these conditions.
- There is an expectation that this information is provided through the printed collateral and brochures available, as well as verbally, to every consumer.
- All healthcare providers including pharmacies, urgent care, general practice, emergency departments and hospital clinicians should consider the possibility of myocarditis/pericarditis in people presenting with the symptoms above, in particular in the days or first few weeks following the vaccine.
- All healthcare providers should review their local clinical pathways on myocarditis/pericarditis investigation and management and ensure they are accessible and known by clinicians.
- The vaccination pathway provides several touch points to share health education on the risk of vaccine-associated myocarditis/pericarditis. They are designed to all work together to raise consumer awareness about the vaccine and include: pre-vaccination screening, informed decision making, vaccinator check of understanding and consent, aftercare observation, and the range of information sheets. Please ensure you are familiar with the requirements of each stage in the process.
- Consider your local workforce education requirements and inform your IMAC regional advisor on any new or specific training needs. This may lead to opportunities for localised, regional, or national targeted training for at risk groups and tailored to local service provision.

Finally, could we ask you to cascade the requirements across your provider network and confirm in writing that local planning and clinical leadership is in place to guide a local response to prevent the serious consequences of undiagnosed or untreated myocarditis/pericarditis.

Ngā mihi

Dr Ashley Bloomfield
Te Tumu Whakarae mō te Hauora
Director-General of Health

Dr Andrew Connolly
Chief Medical Officer

Dr Juliet Rumball-Smith
GM Clinical Quality & Safety
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