SENSITIVE

Office of the Minister for COVID-19 Response

Office of the Minister of Health

Office of the Associate Minister of Health

Cabinet

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, [redacted] 6(a), s 9(2)(j)

[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)

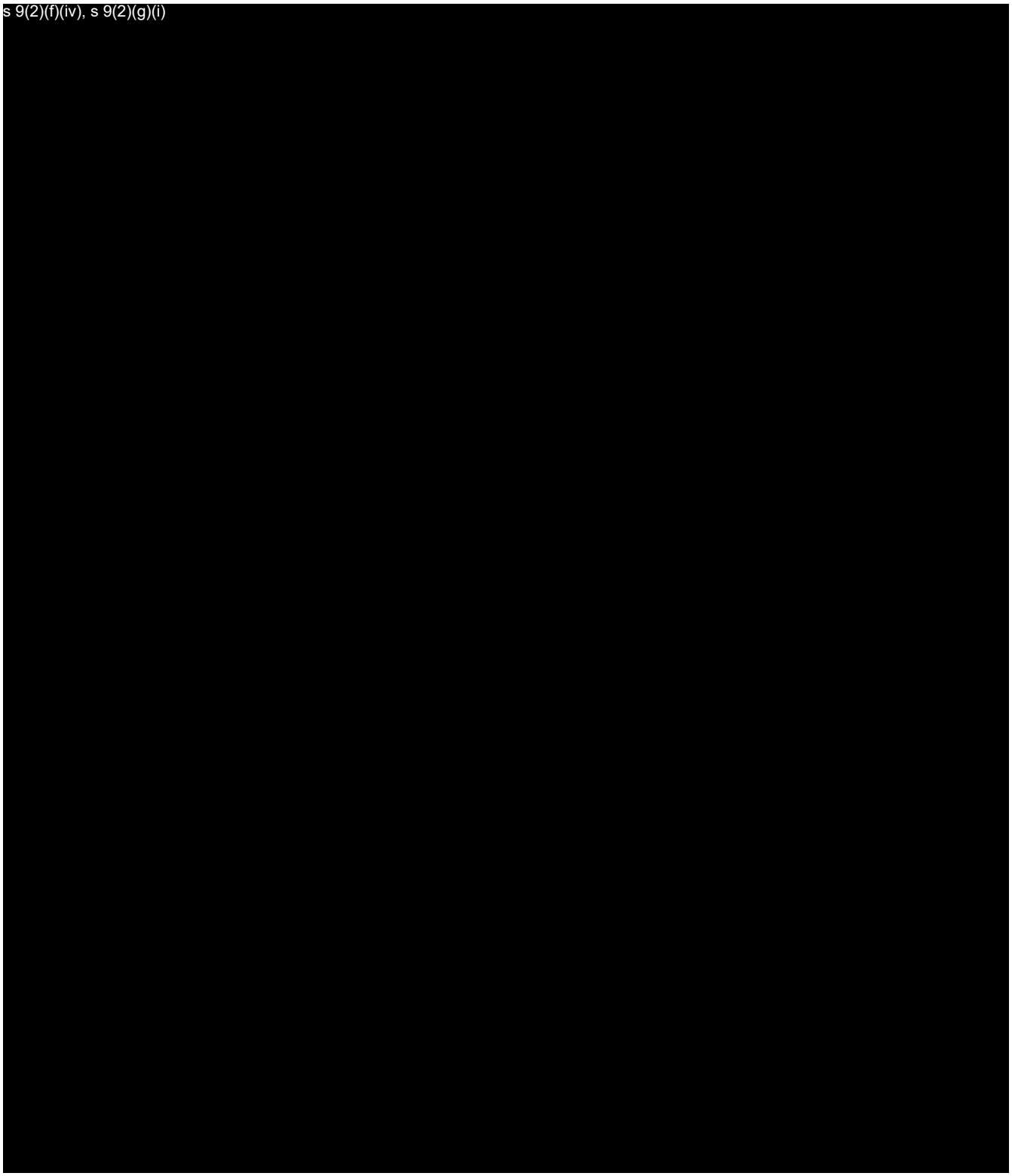
Appendix Two: Information on vaccine candidates as of 20 Jan 2021

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.

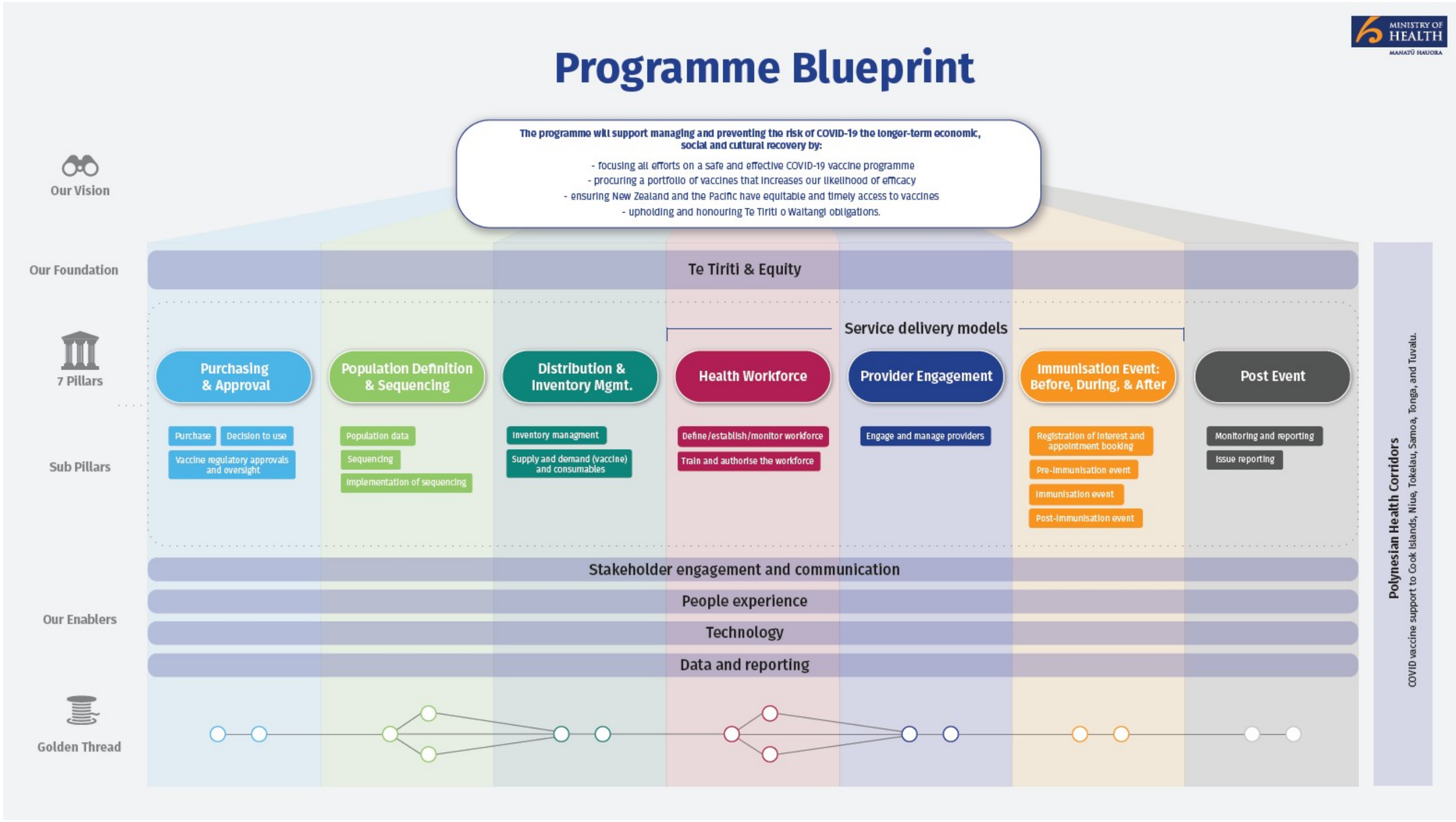
4 It is expected that initial Medsafe approval of any COVID-19 vaccine will be in the form of provisional consent, which can be granted under the Medicines Act 1981 if it is desirable that the medicine be sold, supplied, or used on a restricted basis for the treatment of a limited number of patients.

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