

Budget Sensitive

Office of the Minister for COVID-19 Response

Office of the Minister of Health

Office of the Associate Minister of Health

Cabinet

Update on the COVID-19 Immunisation Strategy and Programme

Proposal

- 1 This paper:
 - 1.1 outlines progress on New Zealand's strategy for COVID-19 immunisation; and
 - 1.2 gives assurance that we can successfully deliver the largest immunisation programme in New Zealand to date, learning from previous immunisation experience.
- 2 It accompanies the Cabinet papers *COVID-19 Vaccine Strategy: Update on vaccine purchasing* and *Support for Pacific and Global Vaccine Access and Roll-out*.

Relation to government priorities

- 3 New Zealand's ability to recover from the COVID-19 pandemic requires obtaining safe and effective vaccines, to implement our preferred immunisation programme at the earliest possible time.

Executive Summary

- 4 The COVID-19 Immunisation Programme will be the largest immunisation programme ever undertaken in New Zealand. It requires significant Information Technology (IT) investment, logistical management, and an uplift in the capacity of the health workforce. Robust governance structures are in place and include external advisory groups as well as senior leadership groups within the Ministry of Health (the Ministry).
- 5 This paper details how we are working to deliver the COVID-19 Immunisation Strategy and Programme, and what we have learnt from experiences with previous immunisation campaigns, especially the 2020 Influenza Immunisation Campaign.
- 6 In respect of COVID-19, this Government has two overarching priorities: to continue the health response to keep New Zealanders safe from the virus; and to drive the economic recovery from COVID-19.

BUDGET SENSITIVE

- 7 COVID-19 immunisation will offer individual protection to immunised individuals initially. Population immunity could be achieved as more people are immunised, which could support the broader economic response to COVID-19 over time. Other public health controls will continue to be an important part of New Zealand's approach to managing the risks associated with COVID-19, as a COVID-19 vaccine will not provide an immediate solution in isolation.
- 8 The COVID-19 Immunisation Strategy and Programme will support the health response and the Elimination Strategy by enabling the best use of any approved vaccines, while upholding and honouring Te Tiriti o Waitangi obligations. To help achieve this, it includes:
 - 8.1 the COVID-19 Immunisation Programme, which provides an 'operational blueprint' for rolling out the vaccine from 1 March 2021, while also providing tools to support higher uptake of immunisation more broadly over the longer term;
 - 8.2 frameworks for making decisions on whether to use any vaccine approved by Medsafe, and how to sequence immunisation as vaccines become available; and
 - 8.3 a comprehensive engagement and communications plan with draft key messages to support public understanding of the programme.
- 9 The COVID-19 Immunisation Strategy is underpinned by the decision-making principles of equity, wellbeing and legacy, and our approach to COVID-19 immunisation is guided by the principles for immunisation:
 - 9.1 the COVID-19 vaccines we deliver will be free and safe
 - 9.2 we will sequence the roll-out as COVID-19 vaccines become available
 - 9.3 the sequencing of access must be needs based
 - 9.4 we will continue to have strong border settings and roll-out strategy until we are confident that the New Zealand population is sufficiently protected.
- 10 The pace, scale, complexity and importance of COVID-19 immunisations means that the Ministry is actively managing a number of risks, such as:
 - 10.1 potential public perceptions towards COVID-19 vaccines. Clear and effective communication will be essential for building people's trust in any COVID-19 vaccine and encouraging uptake, particularly for groups that have historically had lower uptake rates of other vaccines; and
 - 10.2 significant uncertainty around any COVID-19 vaccine's timing, characteristics, effectiveness and safety. In response, preparations for the COVID-19 Immunisation Programme are underway so that it can be ready to be implemented from 1 March 2021.

BUDGET SENSITIVE

BUDGET SENSITIVE

- 11 Medsafe is working to make the regulatory process as efficient as possible. Australia is operating a similar process and is also expecting that COVID-19 immunisation could potentially begin from March 2021.
- 12 While mitigations are in place, a reasonable level of risk will remain.
- 13 We will report back to Cabinet again by the end of February 2021 for approval of the decision-making framework on whether to use a particular COVID-19 vaccine. We will also provide a further update on the approach to sequencing immunisation and an assurance of implementation status.

Background

- 14 In August 2020, Cabinet invited a report back on progress towards developing an Immunisation Strategy for COVID-19, including a 'prioritisation framework' and consideration of access for Pacific countries [CAB-20-MIN-0382 refers]. This paper responds to Cabinet's invitation with an update on the COVID-19 Immunisation Strategy and Programme.
- 15 The accompanying paper *Support for Pacific and Global Vaccine Access and Roll-out* outlines the approach to supporting the Pacific (with a particular focus on Sāmoa, Tonga, Tuvalu and the Realm countries), and other developing countries, to access COVID-19 vaccines and deliver an immunisation programme.

A COVID-19 vaccine could help increase individual and population immunity to support elimination

Aotearoa/New Zealand has an Elimination Strategy for COVID-19

- 16 In respect of COVID-19, this Government has two overarching priorities: to continue the health response to keep New Zealanders safe from the virus; and to drive the economic recovery from COVID-19.
- 17 The Elimination Strategy is our current approach to preventing and minimising harm associated with COVID-19. It aims to eliminate transmission chains in Aotearoa/New Zealand, and to prevent the emergence of new transmission chains originating from cases that arrive from outside the country.
- 18 The availability of a safe and effective vaccine with sufficient uptake may lead to the reconfiguration of other public health measures that support the Elimination Strategy.

A safe and effective vaccine provides the best opportunity to protect individuals from COVID-19

- 19 Unless the virus mutates to become less virulent, or effective therapeutics are developed, a safe and effective vaccine provides the best opportunity to protect individuals from harm.

BUDGET SENSITIVE

BUDGET SENSITIVE

- 20 In the short-term, a safe and effective COVID-19 vaccine can provide some individual protection for those who are immunised. Over time this could help us achieve a level of community protection through population immunity to COVID-19.
- 21 Population (or herd) immunity is achieved when a sufficient number of people are immune so that transmission of the virus stops. This protects those people who have not yet been vaccinated or for whom the vaccine is less effective at producing immunity. Initial modelling suggests that a high degree of vaccine effectiveness and coverage could be required to achieve acceptable health outcomes without additional public health measures. However, this is limited in its usefulness because it does not have accurate information about vaccine efficacy. The actual proportion of the population needing to be vaccinated to achieve population immunity will depend on:
- 21.1 the infectiousness of the virus;
 - 21.2 the efficacy of the vaccine; and
 - 21.3 the nature and duration of protection given by the vaccine (which will only be known after phase IV trials are completed),
- 22 The Ministry will continue to monitor the evidence and modelling around this in relation to COVID-19 vaccines. Phase IV trials are carried out as part of the immunisation roll-out and have variable timings for completion, though generally report on safety at regular intervals. The Ministry is also assessing the feasibility of a New Zealand-based phase IV study of a nationwide cohort, with an emphasis on Māori and Pacific representatives.
- 23 Population immunity would:
- 23.1 protect the health and safety of New Zealanders and safeguard vulnerable groups against the potential harm of COVID-19, and
 - 23.2 reduce our reliance on tools such as strict border measures and lockdowns, which would contribute to economic and social recovery.
- 24 As such, while it is part of the health response, a safe and effective vaccine is likely to also support the economic response to COVID-19 over time. As part of the wider global response, effective COVID-19 vaccines could also help bring the pandemic under control when accompanied by other public health controls. Work is underway to determine the viability of other measures for responding to COVID-19, such as therapeutics.

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

- 25 In May 2020, Cabinet approved the COVID-19 Vaccine Strategy [CAB-20-MIN-0229.01], and in August 2020 agreed to a purchasing strategy [CAB-20-MIN-0382].

BUDGET SENSITIVE

BUDGET SENSITIVE

- 26 More detail on this is in the accompanying Cabinet paper *COVID-19 Vaccine Strategy: Update on vaccine purchasing*, which provides information about the approach to acquiring vaccines and should be read alongside this paper. The costs to date of both the Vaccine Purchasing Programme and the Immunisation Programme have been met through the same *Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency*.

Officials are progressing New Zealand's strategy for COVID-19 immunisation

- 27 The COVID-19 Immunisation Strategy is being developed in parallel with vaccine procurement and is evolving rapidly. Immunisation against COVID-19 will help support the longer-term outcomes that Cabinet has previously agreed to in the COVID-19 Vaccine Strategy [CAB-20-MIN-0229.01 refers]:
- 27.1 sufficient supply of a safe and effective vaccine to achieve population immunity to COVID-19, affordably;
 - 27.2 protection for Māori, Pacific peoples and population groups at particular risk from COVID-19;
 - 27.3 full cultural, social and economic recovery from the impacts of COVID-19;
 - 27.4 recognition of New Zealand as a valued contributor to global wellbeing and the COVID-19 response; and
 - 27.5 New Zealand, Pacific and global preparedness for response to future disease outbreaks.

Analysis

Key guiding principles to our approach to COVID-19 immunisation

- 28 To help New Zealand achieve the above longer-term outcomes, there are a number of key guiding principles that this Government is using for its overall approach to COVID-19 immunisation:
- 28.1 the COVID-19 vaccines we deliver will be free and safe
 - 28.2 we will sequence the roll-out as COVID-19 vaccines become available
 - 28.3 the sequencing of access must be needs based
 - 28.4 we will continue to have strong border settings and roll-out strategy until we are confident that the New Zealand population is sufficiently protected.

BUDGET SENSITIVE

A COVID-19 Immunisation Programme will be the largest immunisation programme undertaken

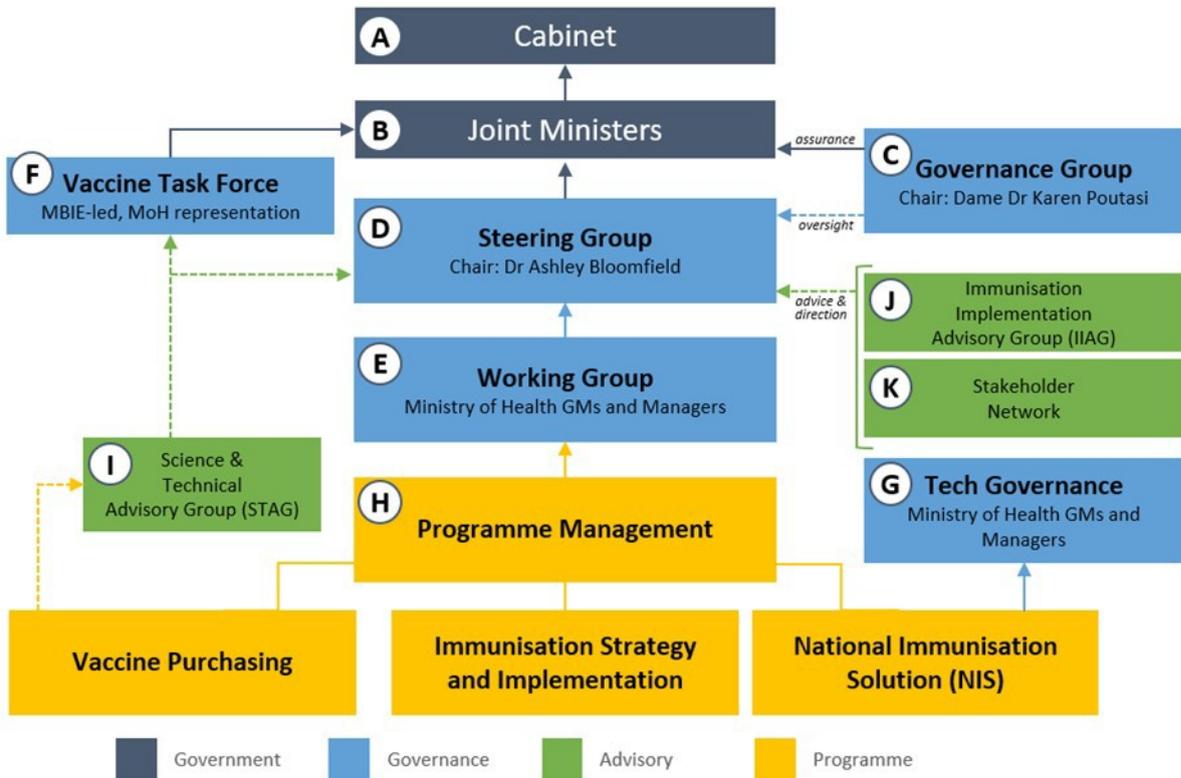
- 29 The COVID-19 Immunisation Programme will be the largest immunisation programme ever undertaken in New Zealand. It aims to immunise as many as possible of the over five million people in New Zealand, the Cook Islands, Niue, Tokelau, Sāmoa, Tonga and Tuvalu. By way of comparison, 1.78 million influenza vaccines were distributed to providers in 2020.
- 30 The challenges of delivering an immunisation programme of this scale include managing the logistics of sourcing and distributing vaccines, developing new IT systems, and training and mobilising the required workforce. Global demand for resources and infrastructure to administer the vaccine is high. To respond to these challenges, work on the COVID-19 Immunisation Programme is progressing at pace and the Ministry are preparing to begin immunisation as soon as possible.
- 31 If the COVID-19 Immunisation Programme is successful, it will support the achievement of the longer-term outcomes listed in paragraph 27. Additionally, the scale of this work means that, along with responding to COVID-19, there is an opportunity to build a world-leading immunisation system. This will include updated information systems, a more diverse and larger workforce, and high levels of public confidence in immunisation as a tool for population health improvement. In turn, this may contribute to better, more equitable health outcomes in the long-term, particularly for Māori and Pacific peoples.

Strong governance will support the successful delivery of the COVID-19 Immunisation Programme

- 32 Robust governance has been established to support the successful delivery of the COVID-19 Immunisation Programme. The governance arrangements include layers of oversight and assurance, which are both internal and external to the Ministry.
- 33 The Governance Group is chaired by Dame Dr Karen Poutasi with representation from within and outside the Ministry of Health and the Steering Group is chaired by the Director-General of Health. The Steering Group is supported by a Science and Technical Advisory Group, an Immunisation Implementation Advisory Group (IIAG), and a Stakeholder Network (see diagram below).

BUDGET SENSITIVE

Diagram One: Governance structure of the COVID-19 Immunisation Programme



We have learnt from previous immunisation experience, especially the 2020 Influenza Immunisation Campaign

- 34 The Ministry of Health has reviewed its experience of rolling out immunisation programmes and has incorporated lessons from this to inform how we deliver the COVID-19 Immunisation Programme.
- 35 A key challenge during the 2020 influenza immunisation programme was knowing where stock was located, and the health sector's ability to move it around was limited.
- 36 In response, the Ministry is developing an inventory management system for COVID-19 vaccines to ensure it has accurate information about where they are located. All storage sites will be secure, and the Ministry will have timely oversight of vaccine volumes and temperature. This will enable us to track and trace COVID-19 vaccines and consumables, including their expiry dates to mitigate wastage.
- 37 This system for the distribution of COVID-19 vaccines centralises all processes within the Ministry, which removes the private/public market split experienced in the influenza programme. A more centralised system will support the Ministry to plan for the COVID-19 Immunisation Programme delivery based on the available supply. A similar system has been developed to support the management and distribution of personal protective equipment (PPE) supplies and is working well.

BUDGET SENSITIVE

B U D G E T S E N S I T I V E

- 38 Likewise, informed by learnings from the 2019 Measles Outbreak response, the Government will be purchasing more than enough COVID-19 vaccine doses for the entire population, and officials have developed a framework for allocating vaccines if stock is limited initially.
- 39 In addition, the Ministry is currently running a Measles Immunisation Campaign which has a strong focus on outreach and access. Planning is also well underway to ensure that the 2021 influenza campaign is successful and builds public confidence in the broader immunisation system. Together with the PPE inventory management system, the Measles and Influenza Immunisation Programmes all work together to test various parts of the system that will support the COVID-19 Immunisation Programme.

We are developing a National Immunisation Solution (NIS)

- 40 Another learning from previous immunisation experiences, such as the 2019 Measles Outbreak, is the need to be able to record accurately who has received a vaccine and when.
- 41 Funding for the NIS, which will replace the National Immunisation Register, has been allocated and work is progressing at pace, with preparations underway in case COVID-19 vaccines arrive earlier than expected. The three phases of delivery are outlined in the table below.

Phases of delivery and indicative requirements for the NIS as at 3 December 2020

1 January 2021	1 March 2021	1 June 2021 and beyond
Interim solution – Basic Immunisation Register	Minimum Viable Product for the NIS	Continued improvement and expanded functionality
<ul style="list-style-type: none"> • Ability to create and maintain a whole of population COVID-19 immunisation record. • Ability to establish an Immunisation Profile for every individual in New Zealand that can be identified by a National Health Index (NHI), in bulk or on a case by case basis. • Ability to link the Immunisation Profiles to existing or new contact details (address, email, phone number). • Ability to load multiple vaccine schedules (i.e. brand, volume, number of doses, timing). • Ability to record vaccination event including consent, identity, vaccine and batch, date, facility, vaccinator etc. • A secure portal accessible 	<ul style="list-style-type: none"> • More sophisticated ability to identify and select individuals for campaigns based on pre-defined criteria. • Ability to engage sequenced cohorts via automated campaigns through multiple channels (mail, text, phone). • Inventory and supply chain management that allows us to track and audit distribution and location of batches and remaining stock to support supply and recall (as required). • Vaccinator Register linked where possible to workers on the Health Provider Index, but with an ability to record the temporary vaccinator 	<ul style="list-style-type: none"> • Enhanced consumer engagement through broader healthcare settings and multiple consumer channels including web and COVID-19 Tracer App • Secure consumer login to access personal health data which could be used to display immunisation status. • Replacement of legacy CARM systems to better support adverse reaction monitoring and pharmacovigilance. • Expanded interoperability with health sector e.g. integration within General Practice Patient Management Systems (and others where relevant) for vaccine delivery, appointment

B U D G E T S E N S I T I V E

B U D G E T S E N S I T I V E

<p>to vaccinators in multiple care settings. Training collateral for existing and new vaccinator workforce.</p> <ul style="list-style-type: none"> • Capability to select or load eligible cohorts for early tranches of sequencing, then to run non-digital vaccination campaigns (manual workforce invitation etc) linked to NHI. • Targeted reporting and analysis including ability to analyse by ethnicity where included in NHI. Reporting on Vaccine stock consumption (i.e. by number of each batch administered), but with manual tracking of stock distribution. • Record of COVID-19 status can be linked to Contact Tracing or Border System records for case investigation purposes using the NHI as an identifier. • Ability to capture adverse reactions at a facility following vaccination and report to Centre for Adverse Reaction Monitoring (CARM). 	<p>workforce (who will not all be registered workforce).</p> <ul style="list-style-type: none"> • Digital media and web-based consumer information about the vaccine. • Bulk funding model to support payments and claiming. • Comprehensive performance monitoring and dashboards, provision of data to support advanced analytics, audit and surveillance. 	<p>booking and to view status.</p> <ul style="list-style-type: none"> • Complete programme to full replacement of the National Immunisation Register for all vaccinations and future pandemic response.
--	---	--

42 The interim solution is a risk mitigation, so that if the clinical trial data and Medsafe approval process is faster than anticipated, we would still be ready to implement before 1 March 2021.

43 Expert representatives will provide real time assurance and oversight of the COVID-19 Immunisation Programme generally, and specifically into the NIS. They will provide regular reporting to the Steering Group, Governance Group and to responsible Ministers.

A comprehensive COVID-19 Immunisation Programme is underway to implement the Immunisation Strategy

44 Success of the COVID-19 Immunisation Programme is dependent on two major work streams, both of which require significant inter-agency consultation and collaboration:

44.1 *Vaccine Purchasing (Vaccine Strategy Task Force)*: Led by the Ministry of Business, Innovation and Employment (MBIE), with support from the Ministry of Health and the Ministry of Foreign Affairs and Trade, focuses on purchasing a portfolio of vaccines [CAB-20-MIN-0382 refers].

B U D G E T S E N S I T I V E

BUDGET SENSITIVE

- 44.2 *Immunisation Strategy implementation*: Led by the Ministry of Health, it includes activities to plan, manage and deliver the vaccine to people in New Zealand.

There are several key components of the COVID-19 Immunisation Programme

- 45 The COVID-19 Immunisation Programme includes the following key workstreams:
- 45.1 **sequencing and defining the population** – identifying and ensuring people get access to a suitable vaccine at the right time, guided by the sequencing framework and population data;
 - 45.2 **an overarching workforce plan** – ensuring the workforce has sufficient capacity and training to deliver COVID-19 vaccines to the New Zealand population, while minimising the impact on other health services;
 - 45.3 **distribution and inventory management** – distributing vaccines kits consistently and efficiently to ensure we have what we need, where we need it, at the right time. This includes the ability to track and trace vaccines and consumables, and monitor supply and demand to adjust stock levels;
 - 45.4 **planning for the immunisation event (before, during and after)** – providing effective scheduling and other mechanisms to support New Zealanders to be immunised;
 - 45.5 **user experience and channels** – providing innovative ways to engage and inform New Zealanders to support their immunisation experience;
 - 45.6 **provider partnership and management** – ensuring safe, efficient and quality service delivery in the right places, tailored to different communities as required; and
 - 45.7 **post-market monitoring** – monitoring safety and efficacy (including, adverse events), with real time reporting on uptake and providing mechanisms that will enable us to adapt our approach if needed.

The Ministry are working through the service delivery models to determine how and where people will receive the vaccine

- 46 The Ministry is planning service delivery models that are aligned to the different scenarios set out under the Sequencing Framework (discussed later in this paper) which will have an impact on how and where the vaccine is delivered. This enables us to identify the different population cohorts as part of sequencing and create a targeted delivery model for each group.
- 47 Ensuring immunisation is accessible is a priority in order to maximise vaccine uptake. Officials are developing locally coordinated solutions that can be delivered in the community. Delivery models being considered include

BUDGET SENSITIVE

BUDGET SENSITIVE

existing models such as General Practitioner (GP) facilities, pharmacies, workplace vaccinations, and models leveraging community pop-up and mobile centres in a range of locations, and at DHB facilities.

- 48 To support high uptake, consumer experience before, during and after people receive their COVID-19 vaccine doses is a key consideration. Officials are actively mapping this against different personas and reaching out to people about their previous vaccine experience to inform the service design.
- 49 An approach worth exploring could be options for a campaign drive around a “COVID-19 vaccine” week to encourage immunisation.
- 50 Engaging with communities, particularly those who are vulnerable and/or are likely to receive the vaccine early, is crucial. Testing and receiving feedback on the proposed service delivery models will be part of the engagement with stakeholders.

Work is progressing at pace to ensure COVID-19 immunisation could begin from 1 March 2021 at the earliest

- 51 Work is progressing at pace across these workstreams to ensure that the COVID-19 Immunisation Programme is ready as soon as approved COVID-19 vaccines become available. Key milestones before 1 March 2021 (our planning assumption date) include:
 - 51.1 there are sufficient vaccinators trained and authorised under the Medicines Regulations 1984 for the sequenced vaccine roll-out, noting that the workforce will continue to scale up beyond March 2021 in line with vaccine delivery schedules;
 - 51.2 inventory management and distribution systems are in place; and
 - 51.3 the required cold chain infrastructure and vaccine consumables are secured.
- 52 An indicative work programme plan with milestones through to 1 March 2021 (the earliest we are expecting vaccines to be available) is attached as **Appendix One**. This plan will continue to evolve as other vaccines are purchased and planning assumptions are finalised.

The purpose of the COVID-19 Immunisation Strategy is to make best use of any vaccines

- 53 The COVID-19 Immunisation Strategy must be able to respond to a range of scenarios. This is because there is some uncertainty associated with COVID-19 vaccines. The level of population immunity that can eventually be achieved is unknown, as this depends on the vaccine effectiveness, how long the vaccine protection lasts, and uptake. For example, if a vaccine only suppresses symptoms it may not reduce the risk of transmission.

BUDGET SENSITIVE

B U D G E T S E N S I T I V E

54 We propose that the COVID-19 Immunisation Strategy’s purpose is to make “best use” of any vaccines while upholding and honouring Te Tiriti o Waitangi obligations and promoting equity. Factors that contribute to “best use” of the COVID-19 vaccines that will be available include:

54.1 ensuring that the right infrastructure is in place to store and distribute COVID-19 vaccines efficiently

54.2 using the proposed Decision to Use Framework and Sequencing Framework (described later in this paper), to use the vaccine to:

54.2.1 respond to the key risks based on the transmission or epidemiological scenario

54.2.2 promote equitable outcomes by protecting Māori, Pacific peoples, older people, disabled people and other population groups at particular risk of the negative health impacts of COVID-19.

54.3 maximise value, by getting the most from the resources available

54.4 encouraging uptake in order to achieve population immunity. For example, through a communications campaign and designing delivery mechanisms that will be responsive to different groups

55 We do not yet know the exact rate of uptake needed to achieve population immunity, as this is dependent on the vaccine characteristics and effectiveness. Details about the actual efficacy and the length of protection will be available after Phase 4 trials are completed.

56 Once officials have more certainty about this “ideal” rate, it can be built into the objectives of the COVID-19 Immunisation Strategy. Officials will seek agreement to a possible uptake goal in the report back on COVID-19 immunisation once they have enough information about vaccine characteristics.

57 It is important to note that some of the population may remain unvaccinated, either by choice, or because they cannot be safely given any of the available vaccines.

58 The COVID-19 Immunisation Strategy consists of:

Strategic frameworks to support decision-making	The framework on whether to use any vaccine once Medsafe (and the Environmental Protection Authority, where relevant as the portfolio may contain vaccines with new organisms) approval is given.
	The framework on sequencing access as vaccines become available.
Delivery	The COVID-19 Immunisation Programme to roll-out the vaccine and encourage uptake.

B U D G E T S E N S I T I V E

B U D G E T S E N S I T I V E

	Technology systems to support the Immunisation Programme and the immunisation system more broadly.
	Post-market release monitoring for effectiveness and safety that enables quick changes to the approach.

- 59 The COVID-19 Immunisation Strategy has several additional considerations underneath the broader Elimination Strategy principles of equity and wellbeing, which are outlined in **Appendix Two**. Another decision-making principle is legacy, given the COVID-19 Immunisation Programme will lead to significant investment into the public health system, which should help New Zealand embed a world class immunisation system with better uptake for groups who traditionally have been harder to reach.
- 60 It is important to acknowledge that COVID-19 immunisation will be voluntary and will require informed consent, and officials are working to encourage uptake. This will include considering what may be needed to support specific communities and sectors to maximise uptake of a COVID-19 vaccine, for example by Māori, disability and Pacific communities and the health or border workforce.

The COVID-19 Immunisation Programme will uphold and honour Te Tiriti o Waitangi obligations

- 61 Upholding and honouring Te Tiriti o Waitangi, including obligations towards Māori that flow from the Treaty partnership and its principles are fundamental to the success of the COVID-19 Immunisation Strategy. Te Tiriti principles and the Ministry of Health's Te Tiriti o Waitangi Framework guide both the development of the COVID-19 Immunisation Strategy, as well as how it will be delivered. Principles such as partnership, tino rangatiratanga, options, equity and active protection are a particularly strong focus.
- 62 As noted earlier, the Ministry has established the Immunisation Implementation Advisory Group (IIAG) to support this work. The Terms of Reference for the IIAG are underpinned by Te Tiriti, and membership of the group includes strong Māori and Pacific representation. The Ministry is working with the IIAG to ensure that the COVID-19 Immunisation Strategy, Sequencing Framework and Programme design honour Te Tiriti and promote equitable outcomes for Māori and Pacific peoples, as well as align with *Whakamaua the Māori Health Action Plan 2020-2025* and *Ola Manuia: Pacific Health and Wellbeing Action Plan 2020-2025*.
- 63 In this, the COVID-19 Immunisation Programme will leverage off the *Updated COVID-19 Māori Health Response Plan* and use existing Māori and Pacific provider networks and communications approaches. Enacting the Tiriti principles will require a commitment to working with and empowering Māori providers to deliver COVID-19 immunisation to their communities.
- 64 Initiatives undertaken in the initial COVID-19 response and the Māori Influenza Vaccination Plan, demonstrated that the Ministry needs to

B U D G E T S E N S I T I V E

BUDGET SENSITIVE

adequately resource and fund providers and DHBs to establish Māori-led, Māori-focused programmes in a high-trust, permissive environment.

- 65 During the COVID-19 response, Māori communities and organisations mobilised immediately in the initial lockdown to respond to the needs of their community, providing holistic, whānau-centred care. These communities and organisations are trusted by local communities and are key to the successful roll-out of the COVID-19 Immunisations Programme.
- 66 To achieve equity, the Ministry are proactively working to ensure that service design provides for groups the system has historically failed to reach, such as Māori in rural areas. This may require new solutions, and planning is underway for appropriate service design models, including community-based immunisation centres (for example, mobile centres). The Ministry is continuously testing and developing its thinking with the IIAG and will also engage with the Tumu Whakarae (the General Manager Māori network across the DHBs).
- 67 Strong community partnerships are crucial to building trust in the COVID-19 vaccine and the approach to immunisation, which we believe will support better uptake. The Ministry will continue to explore further opportunities for partnership with iwi, hapū and other stakeholders and community groups, which could include:
- 67.1 how to best communicate and engage with those that they represent; and
 - 67.2 supporting administration and distribution of COVID-19 vaccines.
- 68 Further detail on our engagement approach is outlined later in this paper.

Immunisation can only begin once Medsafe have approved the COVID-19 vaccine for use

- 69 In order for medicines to be available for use in New Zealand, they must be approved under the Medicines Act 1981. Medsafe is the independent responsible body for delivering this approval, and determines whether medicines, including vaccines, are safe for use in New Zealand. The approval process for a new medicine (including vaccines) includes an assessment of a dossier of data covering non-clinical, clinical and manufacturing studies.
- 70 This independent regulatory process provides surety and transparency to help maintain public trust that vaccines meet acceptable standards of safety, quality and efficacy.
- 71 Unlike in other countries, New Zealand does not have widespread community transmission or loss of life, so the Ministry do not propose using an emergency use authorisation process to approve a vaccine in advance of complete clinical trial information. To do so would potentially compromise our assurance of the safety, quality, and efficacy of the COVID-19 vaccines.

BUDGET SENSITIVE

B U D G E T S E N S I T I V E

Medsafe have adopted several options to ensure timely assessment

- 72 While Medsafe is prioritising assessment of COVID-19 vaccines, officials cannot predict with certainty when this approval process will be completed.
- 73 This is because the date of Medsafe approval largely depends on when the pharmaceutical company provides the data, the quality of that data, and whether it is a full or abbreviated assessment process (where it evaluates assessments from other recognised overseas regulators, such as the European Medicines Agency).
- 74 To facilitate the approval process for COVID-19 vaccine candidates, Medsafe has agreed to accept rolling submissions from companies, which means that companies can provide data in tranches as it becomes ready for assessment. The table below outlines an example what a typical rolling submission might look like:

Dec 2020	Jan 2021	Feb 2021	March 2021	April 2021
Non-clinical	Quality #1	Clinical Phase I, II	Quality #2	Clinical Phase III

- 75 In addition, Medsafe has additional expert resources available and will be able to assess up to four COVID-19 vaccine applications simultaneously should the timeframes overlap.
- 76 Medsafe has been in regular contact with companies, specifically those that New Zealand have Advance Purchase Agreements with or are in negotiations. Companies have indicated their preferred approaches for submission and Medsafe is already receiving submission data on vaccine candidates.

Australia is operating a similar regulatory process for COVID-19 vaccines

- 77 Australia have published information on their COVID-19 Vaccination Policy online. Like New Zealand, they are purchasing a portfolio of vaccines, with expected delivery beginning in early 2021.
- 78 Immunisation will be free in Australia, except for a few specified visa types. Priority is likely to be given to people:
 - 78.1 at increased risk of exposure
 - 78.2 at increased risk, relative to others, of developing severe disease or outcomes
 - 78.3 those working in services critical to societal functioning.
- 79 Like New Zealand, Australia is expecting COVID-19 vaccines to be rigorously assessed for safety, quality and efficacy, using clinical trial data, before they can be approved for use. This is done by the Therapeutic Goods Administration (TGA), advised by the independent expert Advisory Committee of Vaccines. Medsafe are working closely with the TGA to ensure that we are

B U D G E T S E N S I T I V E

well-connected and can share information. ^{6(b)(i)} [REDACTED]

80 Australia’s Minister of Health has stated publicly that Australia is “on track to deliver vaccines to Australians, commencing in March 2021.” This is subject to TGA approval, which, all going well, could be expected by the end of January 2021 for the first COVID-19 vaccines.

Immunisation will likely need to be sequenced initially, and a framework has been developed for doing this

81 Initially, vaccine supply may be limited, so officials have developed a Sequencing Framework to ensure the right people have access to the right vaccine at the right time, while upholding and honouring Te Tiriti o Waitangi obligations. The Framework is equity driven and aims to protect vulnerable populations.

82 A summary of the current Sequencing Framework outlining the overall approach and methodology is in **Appendix Three**. Advice and evidence from international and New Zealand experiences is rapidly evolving so the current Sequencing Framework will be updated as new information becomes available.

83 The Sequencing Framework would be applied once the decision to use a vaccine has been taken, and when complete information about the characteristics (suitable populations, effectiveness, and available volume) of a vaccine is available.

84 The Sequencing Framework outlines the order in which access to a vaccine would be made available to at-risk populations. The Ministry have planned for three transmission scenarios, each with a specific objective:

Epidemiological Scenario	Objective
Low/no transmission	To prevent transmission
Controlled outbreaks	To reduce transmission and protect people closely connected to an outbreak
Widespread transmission	To protect those who are most vulnerable to serious health outcomes

85 To effectively protect all New Zealanders, particularly the most vulnerable, the Framework categorises four population groups – those at greater risk of:

- 85.1 infection;
- 85.2 transmission;
- 85.3 more serious health outcomes; and
- 85.4 poor cultural, social and economic outcomes.

BUDGET SENSITIVE

- 86 For a particular scenario and a particular vaccine, a portion may first be set aside for contingency. Then the vaccine would be allocated to populations identified in the first tier (as the first line of defence), then a second and third tier. There is provision for further refinements (using assessment criteria) where there is insufficient vaccine to cover all groups within a tier.
- 87 Under all scenarios people at increased risk of serious health outcomes, such as older people, will receive the vaccine ahead of the general population.

Low/no transmission scenario

- 88 **Appendix Three** includes a hypothetical example to illustrate how the Framework would be applied in the no/low transmission scenario. The objective is to prevent transmission, so tier one includes border, managed isolation and quarantine (MIQ) workers, highest risk frontline healthcare workers, and their household contacts. Tier two then includes the rest of the at-risk health workforce, and at-risk people in essential public sector and private industries. Tier three includes those most vulnerable to serious illness such as older people.
- 89 In the low/no transmission scenario, vaccinating those who are closest to the border and potential cases, is likely to provide the best protection for the whole population, including Māori, Pacific peoples, disabled people and older people.

Widespread community transmission scenario

- 90 In the widespread community transmission scenario, the objective is to protect those most at risk of serious health outcomes, so tier one includes vulnerable people, particularly older people and people with relevant disabilities or health conditions.

The Ministry will continue to refine the Sequencing Framework

- 91 The Ministry will continue to engage with stakeholders such as the IAG on the Sequencing Framework, with more detail later in the paper on the engagement approach. It is important to note that given the characteristics identified in the Sequencing Framework, it will be important to partner with stakeholders such as employers and other government agencies on the implementation of the Sequencing Framework.
- 92 Likewise, officials continue to review evidence around the best approach to sequencing based on which groups are most at risk.
- 93 We will report back to Cabinet on progress on the Sequencing Framework by the end of February 2021. We will also report back if advice from officials suggests the Sequencing Framework needs to be substantially altered in line with new information.

BUDGET SENSITIVE

BUDGET SENSITIVE

There needs to be a decision to use any vaccine

- 94 If a Medsafe (and where relevant, the Environmental Protection Authority) approved vaccine becomes available, there needs to be a decision to use it. This is because we intend to purchase a portfolio of vaccines, so New Zealand is likely to be in a situation where we can make a choice about which vaccine to use and when.
- 95 As an example, if Vaccine A has been approved and it would protect 70 percent of immunised people, but if officials receive further information that Vaccine B would protect 90 percent and is only a couple of weeks away, it may be preferable to decide to use Vaccine B as opposed to Vaccine A. Officials are working through what would happen to a COVID-19 vaccine if we decided not to use it, but options could include donation to other countries.
- 96 To help guide this decision, we have directed officials to develop a framework for deciding to use an approved COVID-19 vaccine. The 'Decision to Use Framework' is expected to consider:
- 96.1 the rest of the vaccine portfolio likely to be available in the near future – for example, it may be better not to use a vaccine if it is likely that another, more effective vaccine will be available soon;
 - 96.2 the impacts on the Pacific;
 - 96.3 the impact on the implementation of the Sequencing Framework; and
 - 96.4 the costs, benefits and risks associated with the use of a vaccine, such as evidence about its effectiveness.
- 97 We will report back to Cabinet by the end of February 2021 for agreement on this Decision to Use Framework. This would then be applied following Medsafe approval of COVID-19 vaccines.

We will be supporting vaccine access for the Pacific

- 98 Supporting the Pacific, in particular our six Polynesian Health Corridors partners (the Cook Islands, Niue, Tokelau, Sāmoa, Tonga and Tuvalu) to access and distribute a COVID-19 vaccine is consistent with our historic partnerships with the region and our strong ties with Pacific communities.
- 99 The accompanying Cabinet paper, *Support for Pacific and Global Vaccine Access and Roll-out*, outlines the approach to this and seeks agreement to funding to support COVID-19 immunisation in the Pacific. Support for the six Pacific countries will be offered through the new Pandemic Preparedness workstream under the Polynesian Health Corridors Programme, which is managed by the Ministry of Health. This sits alongside New Zealand's COVID-19 Immunisation Programme.
- 100 The intention is to uphold our obligations to the Realm as part of our binding commitment with the COVAX Facility for coverage of 50% of the population of

BUDGET SENSITIVE

the Realm of New Zealand, and our commitments to directly support equitable access and roll-out for the other participant Pacific countries.

101

s 9(2)(f)(iv)



102 In addition, our communications will reach some people in these countries through their transnational networks with New Zealand. This will be one channel for responding to vaccine hesitancy in the Pacific.

Clear and effective communications are critical to the success of the COVID-19 Immunisation Programme

103 Clear, effective engagement and communications have been fundamental to the success of the COVID-19 response to date, and this will continue with the COVID-19 Immunisation Programme. We have asked the Ministry to have a strong engagement process to support the public's understanding of COVID-19 vaccines. They are aiming to build trust and confidence in the COVID-19 Immunisation Programme, which in turn can encourage people to be immunised.

104 As outlined earlier, the Ministry has a strong focus on working with Māori as partners to uphold Te Tiriti principle of partnership, with engagement already underway and expected to continue throughout the COVID-19 Immunisation Programme. The Crown has a special relationship with Māori that must be reflected in our engagement approach. The Ministry meets fortnightly for three hours with the IIAG to discuss wide ranging aspects of the COVID-19 Immunisation Programme. Recent discussions have been on the engagement and communications strategy, Sequencing Framework, immunisation service design and workforce matters.

105 The Ministry has also started ongoing collaboration with members of the Iwi Communications Network on what will become a shared engagement approach that is expected to include one-to-one meetings, workshops on key topics and potential concerns/barriers, and ongoing agenda-item updates at existing hui by invitation. The Ministry have also met with the COVID-19 Māori Monitoring Group and expressed a desire to partner together on the engagement approach.

106 Similar activity is underway to develop a jointly agreed engagement plan with Pacific people stakeholders and other key stakeholder groups (the health workforce, other ethnic groups, commercial sector, education, disabled people, border workforce, faith communities and others). The Ministry expects to begin to engage with these identified stakeholders before the end of the year or early next year.

B U D G E T S E N S I T I V E

- 107 Given the work underway to establish a shared engagement approach, we propose that the Ministry starts to engage with the wider external stakeholder networks on the COVID-19 Immunisation Strategy and Programme before the end of the year. The focus of this engagement would include the COVID-19 Immunisation Programme service design, communications campaign and the Sequencing Framework.
- 108 In addition, the Ministry will continue its discussions with the IAG and district health boards (DHBs).

The Ministry is preparing for a communications campaign that can build confidence and trust in the COVID-19 vaccine

- 109 Regular, credible and accessible communication will continue throughout the COVID-19 Immunisation Programme, drawing on the many existing platforms, channels and networks that were used during the initial COVID-19 outbreak and the following resurgence.
- 110 The Ministry are working to confirm a broader team of spokespeople for the COVID-19 vaccine and immunisation programmes. The proposed team includes:
- 110.1 Dr Ashley Bloomfield, Director-General of Health;
 - 110.2 Dr Nikki Turner, Director of the Immunisation Advisory Centre (IMAC);
 - 110.3 Dr Rawiri Jensen, Ngāti Raukawa, General Practitioner and Clinical Director of the National Hauora Coalition;
 - 110.4 Dr Api Talemaitoga, General Practitioner; and
 - 110.5 Dr Helen Petousis-Harris, vaccinologist and Associate Professor at the University of Auckland.
- 111 The Ministry are working to identify a number of other health practitioners and clinicians, including nurse practitioners, who could be supported to speak directly to their communities. We will also consider other possible influential spokespeople, such as entertainment figures or athletes.
- 112 The broader public information campaign approach is expected to deliver:
- 112.1 a broadly targeted campaign for general audiences;
 - 112.2 targeted campaigns to reach Māori communities;
 - 112.3 targeted campaigns to reach Pacific communities; and
 - 112.4 translated materials (including into accessible formats, Pacific languages and New Zealand Sign Language), for use in a wide range of networks for distribution.

B U D G E T S E N S I T I V E

B U D G E T S E N S I T I V E

- 113 There will be three key components to the communication campaigns which seeks to:
- 113.1 **Support informed decisions:** inform people about the nature of the vaccines, how they work on the virus and how we can have confidence that they are safe.
 - 113.2 **Address barriers to immunisation:** respond to any key areas of question and concern that may create vaccine hesitancy. Officials have commissioned further research to help identify and understand specific attitudes, perceptions, questions and concerns.
 - 113.3 **Encourage uptake:** lead the drive to maximise the level of immunisation.
- 114 The first two components can begin in the next month. The third component should start once we have confirmed COVID-19 vaccines for roll-out. The communications campaigns are expected to span at least an 18-month period.
- 115 The significant number of unknowns at this time can make delivering a clear narrative challenging, and there is a risk of contradictory information being shared in the public domain. Officials will take an agile approach to managing any misinformation that arises and will share information transparently. Likewise, they will provide updates on New Zealand’s approach, including clarifying any similarities and differences with approaches in other countries
- 116 Additional detail on the Ministry’s draft key messages for the communications campaign, is included in **Appendix Four**.

Implementation

Expected delivery timeframes

- 117 The table below outlines current information on when the Ministry expects to receive COVID-19 vaccines:

Vaccine candidate	Courses purchased	Doses per course	Delivery scheduled (courses)
Pfizer/BioNTech	750,000	2	s 9(2)(j)
Janssen	5 million	1	
<i>Viral vector vaccine (exact delivery schedule to be confirmed)</i>	3.8 million	2	

B U D G E T S E N S I T I V E

B U D G E T S E N S I T I V E

- 118 Based on this, the Ministry’s planning assumption is that the COVID-19 Immunisation Programme must be ready to be implemented from 1 March 2021 to ensure that the Ministry’s systems do not delay the roll-out of the COVID-19 Immunisation Programme. Activity is expected to ramp up over the course of 2021.
- 119 Officials will provide Ministers with further advice and updates on a range of matters related to the COVID-19 Immunisation Programme throughout January and February 2021, such as:
- 119.1 the Decision to Use and Sequencing Frameworks;
 - 119.2 eligibility to publicly funded COVID-19 immunisation;
 - 119.3 the approach to any General Practitioner co-payment, and other related matters;
 - 119.4 the engagement and communications approach;
 - 119.5 if needed, regulatory changes to support the new vaccinator workforce;
 - 119.6 the “immunisation event” service design; and
 - 119.7 if possible, the use of approved COVID-19 vaccines.

The Ministry is actively managing risk to ensure successful delivery of the COVID-19 Immunisation Programme

- 120 Given the uncertainty around when regulatory approval will be given, and potentially short implementation timeframes, the Ministry is managing several risks.
- 121 It is actively mitigating these, and the approach for key risks is outlined in the table below:

Risk	Description	Mitigation
Supply chain	Manufacturers may have limited capacity to meet demand as there will be high global demand.	Sequencing Framework for allocating the vaccine if stock is limited. Including representatives with supply chain expertise at operational and governance level.
	Specific requirements for transporting the vaccine may be needed to maintain the integrity of the supply chain.	Purchasing infrastructure and consumables to meet these specific requirements.
Public perceptions of the vaccine	The public may be reluctant to receive the vaccine if they perceive that it is unsafe, or there is misinformation in the public domain. This could lead to low uptake and New Zealand may not achieve	We will be working with trusted community leaders and navigators to promote key messages that can support understanding and informed decision-making. The work to identify appropriate leaders has begun through discussions with the Immunisation Implementation Advisory

B U D G E T S E N S I T I V E

B U D G E T S E N S I T I V E

	<p>population immunity. It could also have an impact on equitable outcomes if uptake is lower for particular groups, such as Māori and Pacific peoples.</p>	<p>Group and will be built upon through wider stakeholder networks and relationships with other agencies, such as Ministry for Pacific Peoples, Te Puni Kōkiri and the Department for Internal Affairs.</p> <p>Key messages will make it clear that the approval process is independent and will be followed as usual, to help assure the public that the vaccine is safe to use.</p> <p>Further work is being done on vaccine hesitancy and options for encouraging uptake (including for different groups) and managing misinformation in the public domain.</p>
Workforce	<p>A constrained workforce, both in terms of capacity and capability, could undermine the ability to immunise the population. At the same time, the Ministry need to ensure core health and disability work, and regular immunisation programmes can continue. Previous workforce modelling suggested the Ministry would need to train additional people to deliver the COVID-19 vaccine alongside other immunisation programmes and health services.</p>	<p>This Ministry has developed a workforce plan, which covers:</p> <ol style="list-style-type: none"> 1. utilising the current workforce 2. training for other health professionals, e.g. Kaiāwhina 3. recruiting new vaccinators such as those without current practice certificates. <p>Currently there are around 12,000 health professionals capable of vaccinating in New Zealand.</p> <p>As part of the workforce plan the Ministry will engage an additional core vaccinator workforce of between 2,000 – 3,000 vaccinators to add to the existing capacity. This will result in a total workforce of around 15,000 people across New Zealand. Modelling has shown that the core workforce (of 2,000 – 3,000 vaccinators) is likely sufficient to deliver the vaccine in New Zealand. However, using the existing capacity as well will support better access and equitable delivery of a vaccine across New Zealand. Ensuring that New Zealand has a diverse and culturally capable workforce will also be a key focus.</p>
Adverse health reactions	<p>It is possible there may be unexpected health outcomes such as adverse reactions. This has the potential to undermine the COVID-19 Immunisation Strategy and immunisation more broadly.</p>	<p>Developing an enhanced pharmacovigilance system to support monitoring in real time of any adverse reactions.</p> <p>This would give the Ministry the ability to identify and then halt or recall any vaccine that has a negative impact on the population.</p>
New IT platform in tight timeframes	<p>The NIS platform will be critical to the success of the Immunisation Programme and needs to be delivered in the short-term.</p>	<p>A phased solution is being developed:</p> <ol style="list-style-type: none"> 1. an interim solution will be ready by 1 January 2021. 2. a more complete NIS will be available on 1 March 2021 that will be able to support improved capability.

Financial Implications

122 Officials have been refining the cost estimates of COVID-19 vaccines and the COVID-19 Immunisation Programme.

B U D G E T S E N S I T I V E

B U D G E T S E N S I T I V E

- 123 The cost of the Programme depends on when approved vaccines become available, their characteristics and uptake. There is still uncertainty around these factors. Cabinet noted that the full cost of COVID-19 immunisation was likely to be higher than the tagged contingency once fully costed; and agreed in principle that additional costs be provided from the COVID-19 Response and Recovery Fund [CAB-20-MIN-0382].
- 124 As expected, the cost of purchasing and rolling out vaccines will exceed the § 9(2)(f) set aside by Cabinet in the *Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency* [CAB-20-MIN-0382]. This reflects that the COVID-19 Immunisation Programme would be the largest publicly funded immunisation campaign to date.
- 125 Note that the COVID-19 Immunisation Programme costings have been prepared on the basis that the COVID-19 vaccine would be free. We have directed officials to provide further 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.
- 126 The table on the next page outlines the revised cost estimates for the Programme, alongside estimated costs for vaccine purchasing. Detailed indicative costings for the COVID-19 Immunisation Programme are attached in **Appendix Five**.

Estimated costs for the Vaccine Purchasing and Immunisation Programme

	\$million – increase / (decrease)				
	2020/21	2021/22	2022/23	2023/24 & outyears	Total
Vaccine Purchasing	§ 9(2)(f)(iv)	-	-	-	§ 9(2)(f)(iv)
Immunisation Programme	§ 9(2)(f)(iv)	§ 9(2)(f)(iv) (only estimated to December 2021)	*	*	§ 9(2)(f)(iv)
Estimated total investment	§ 9(2)(f)(iv)	§ 9(2)(f)(iv)	-	-	§ 9(2)(f)(iv)

* *Costings are still being refined for these periods but are expected to be significantly lower.*

- 127 To date, \$66.30 million has been drawn down from the tagged contingency, with an additional § 9(2)(f)(iv) million for the COVID-19 Immunisation Programme still required up to December 2021.

B U D G E T S E N S I T I V E

B U D G E T S E N S I T I V E

128 The accompanying paper *COVID-19 Vaccine Strategy: Update on vaccine purchasing* will provide the full estimated fiscal implications across the COVID-19 Vaccine Purchasing and Immunisation programmes and seeks additional funding to support the COVID-19 Immunisation Programme.

National Immunisation Solution

129 Ministers recently approved the business case for the National Immunisation Solution and appropriated contingency funding for the system’s implementation (through a separate contingency), with a small contribution from existing Vote Health baselines.

130 The expected cost is shown in the table below. If there is need for additional funding it is expected that this can be managed through funding appropriated for the COVID-19 Vaccine and Immunisation Programmes.

Estimated costs for the National Immunisation Solution

	\$million – increase / (decrease)				
	2020/21	2021/22	2022/23	2023/24 & outyears	Total
National Immunisation Solution	s 9(2)(f)(iv)				

Legislative Implications

131 This Cabinet paper has no legislative implications.

Impact Analysis

Population Implications

132 The COVID-19 Immunisation Strategy has been developed to enable best use of COVID-19 vaccines to support the immediate health response to COVID-19 in New Zealand and the Pacific. Delivering on the COVID-19 Immunisation Strategy may contribute to the full cultural, social and economic recovery from COVID-19.

133 This has potential flow-on implications for specific population groups at increased risk of adverse social, cultural and economic outcomes. For example, some groups are more likely to experience difficulty in returning to employment and subsequent economic hardship over the long-term, such as disabled people, Māori, Pacific peoples and young people who have recently entered the labour market. Employment rates for women have also decreased significantly in the September quarter.

134 In addition, vulnerability to the health effects of COVID-19, including death, could disproportionately affect older people and people with underlying conditions. Disabled people, Māori and Pacific peoples are also more likely to experience these impacts, as they have higher rates of underlying health conditions and co-morbidities. Those who live in crowded housing, for

B U D G E T S E N S I T I V E

BUDGET SENSITIVE

example, living in an intergenerational arrangement, or those who work in particular roles such as border security, are also likely to be more at risk of transmission. Promoting equity for these groups is a focus of the Sequencing Framework, which will determine who receives the vaccine when.

Human Rights

- 135 The COVID-19 Immunisation Strategy acknowledges that all individuals are equally deserving of care and that vaccination will be voluntary. It is important to note that depending on the vaccine characteristics, some groups may not be able to be vaccinated if it is not approved for use for certain population groups.
- 136 Vaccines may be made available earlier to certain persons or groups of persons if supplies are limited. This is based on reducing public health risks (at either an individual or community level).
- 137 Where sequencing of immunisation is required, COVID-19 vaccine allocation will be guided by the Sequencing Framework described earlier in the paper, which aims to best protect all New Zealanders from the potential harm of COVID-19, while promoting equitable outcomes.
- 138 Officials continue to review evidence around which groups would be most vulnerable to the above risks to inform the Sequencing Framework. Depending on the available evidence, individuals may be eligible to receive a COVID-19 vaccine sooner on the basis of having a disability or health condition, being a certain age, sex, ethnicity, or family status.
- 139 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 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

- 140 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 and Te Puni Kōkiri. The Department of the Prime Minister and Cabinet has been informed.
- 141 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.

BUDGET SENSITIVE

Comment from The Treasury

- 142 The Treasury supports this paper, which outlines the best efforts possible at this stage to ensure that a successful vaccine (if available) can be rolled out as early as 1 March 2021. However, whilst some mitigations are in place (including strong governance), there remains a reasonable level of risk given the pace, scale, complexity and strategic importance of this initiative. If a vaccine is approved for use in New Zealand, the immunisation programme will be the largest ever undertaken in New Zealand. There are multiple critical components that we need to line up in order for the Programme to be successful, including access to supply chain needs, consumables and the required technology, and having a workforce ready to deliver the vaccine.
- 143 The impacts of not running a successful Immunisation Programme extend beyond the response to COVID-19, most significantly in terms of the wider perceptions of vaccine programmes, as well as public trust and confidence in the health system. The revised delivery date of 1 March 2021 provides the necessary time to bring together the critical service design components. Given the significant impacts associated with failure to deliver, we recommend that future decisions about the roll-out of vaccines should be based on an assessment of readiness to implement the Immunisation Programme rather than vaccine availability.
- 144 The level of funding outlined in the paper is commensurate to the challenge ahead. Appropriating the funding for the Immunisation Programme now minimises the risk of funding delays leading to delivery delays, with fiscal discipline managed through regular reporting. We note that the ongoing costs of the Immunisation Programme remain uncertain and that the funding sought is expected to cover one round of the programme.

Communications

- 145 The COVID-19 Immunisation Programme communications campaign will be an iterative process and is essential to maintain trust. Further details about the communications approach is outlined earlier in the paper.

Proactive Release

- 146 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 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 refers]

BUDGET SENSITIVE

- 2 **Note** that this paper should be read alongside the accompanying papers *COVID-19 Vaccine Strategy: Update on vaccine purchasing and Support for Pacific and Global Vaccine Access and Roll-out*
- 3 **Agree** that this 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 **Note** that these guiding principles are consistent with the overarching Elimination Strategy principles of equity and wellbeing
- 5 **Agree** 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 **Note** that the COVID-19 Immunisation Programme would be the largest immunisation programme undertaken in New Zealand to date
- 7 **Note** 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 **Note** 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 **Note** 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

BUDGET SENSITIVE

BUDGET SENSITIVE

- 10 **Agree** that the Ministry of Health starts to engage with other external stakeholder networks on the COVID-19 Immunisation Strategy and Programme before the end of 2020
- 11 **Note** 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 **Note** 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 **Agree** to officials developing a framework on the “decision to use” any approved vaccines available, as there will likely be a number of trade-offs to consider
- 14 **Note** 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**
- 15 **Agree** 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 **Agree in principle** to the current Sequencing Framework, noting that it will be updated to reflect new and emerging evidence
- 17 **Invite** the Minister of Health to report back in 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 **Note** that updated estimates indicate that the COVID-19 Immunisation Programme costs are now estimated at ^{s 9(2)(f)(iv)} 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 **Note** 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 **Note** 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 **Note** the accompanying paper *COVID-19 Vaccine Strategy: Update on vaccine purchasing* provides the full estimated fiscal implications across the

BUDGET SENSITIVE

B U D G E T S E N S I T I V E

COVID-19 Vaccine Purchasing and Immunisation Programmes and seeks agreement to the additional funding required.

Authorised for lodgement

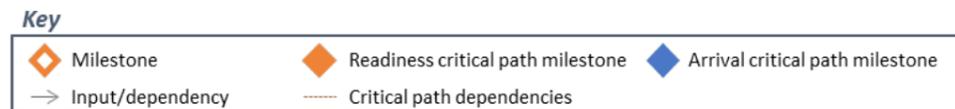
Hon Chris Hipkins
Minister for COVID-19 Response

Hon Andrew Little
Minister of Health

Hon Dr Ayesha Verrall
Associate Minister of Health

B U D G E T S E N S I T I V E

Appendix One: High-level plan for delivering the COVID-19 Immunisation Programme (version as at 30 November 2020)



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 <i>(Elimination Strategy decision-making principle)</i>	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 <i>(Elimination Strategy decision-making principle)</i>	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	

BUDGET SENSITIVE

Appendix Three: COVID-19 Vaccine Sequencing Framework as at November 2020

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, by

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

- Low/no community transmission → To prevent transmission
- Clusters/controlled outbreaks → To reduce transmission, protect people in close contact
- Widespread outbreaks/community transmission → To protect the most vulnerable by preventing serious illness and mortality.

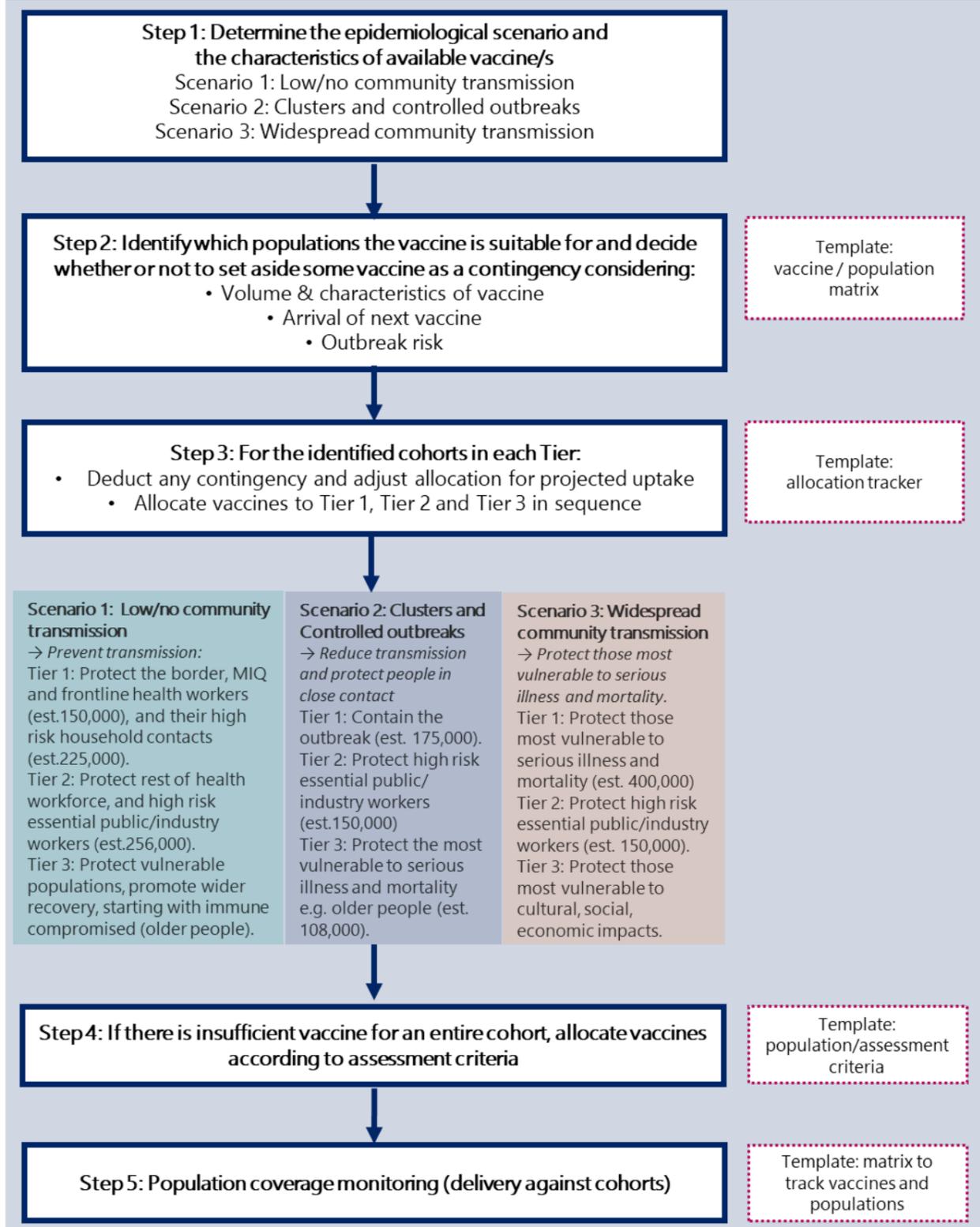
Vulnerable communities - we have identified four (overlapping) groups more at risk of...

- 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
- *Māori and Pacific people are likely to be over-represented in groups 2-4

Change protocol

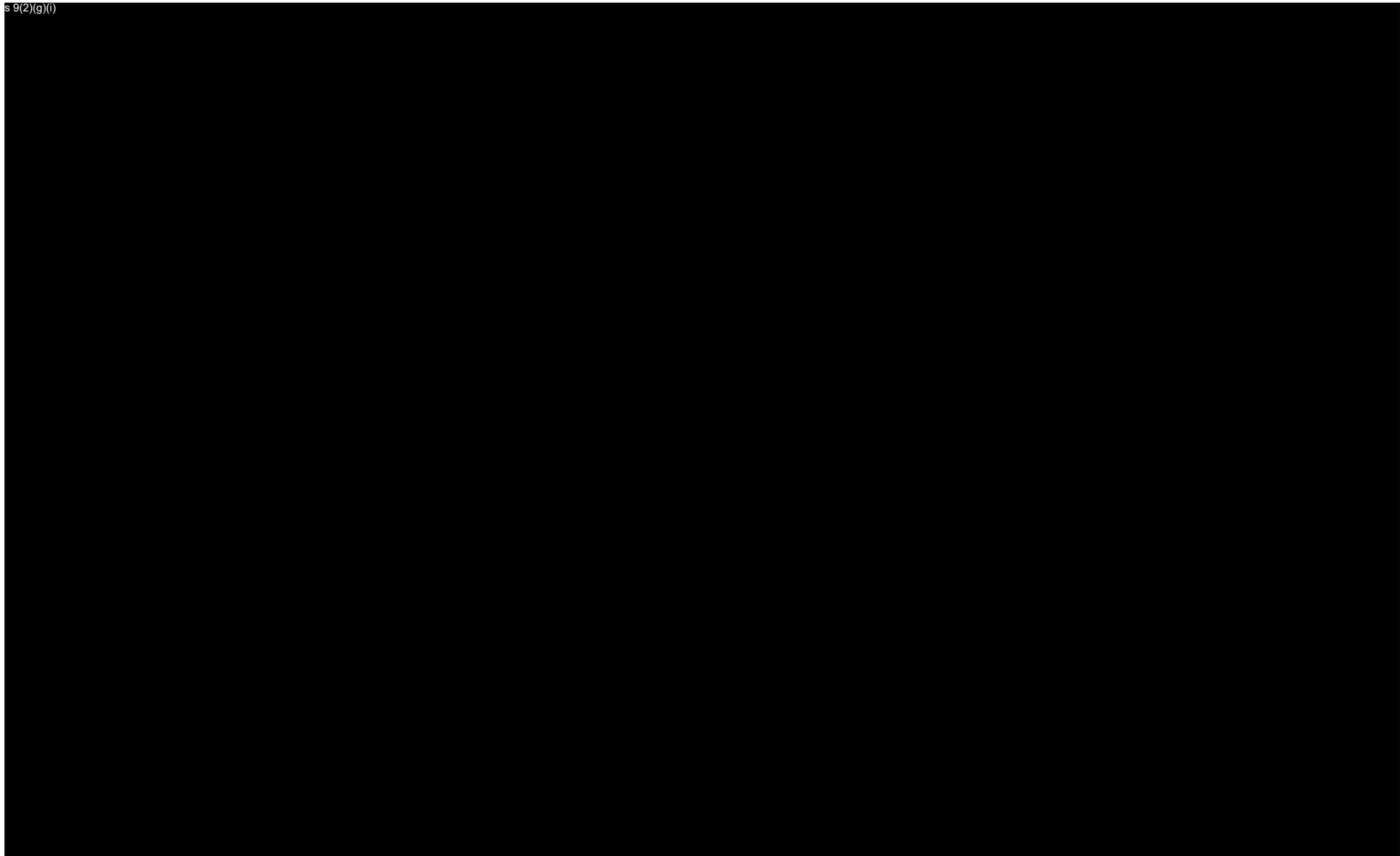
- Emerging guidance, advice, analysis, and evidence will be reviewed and appropriate changes made to strengthen the Framework. The Ministry will provide advice to Ministers, programme advisors and the Governance Group where substantive changes are proposed.

Part B: Sequencing Framework - Methodology



BUDGET SENSITIVE

Appendix three continued



s 9(2)(g)(i)

Appendix Four: Communications and engagement approach for COVID-19 Immunisation – key messages

The communications and engagement strategy are being jointly developed between the Ministry of Health and MBIE to reflect the goals of the Vaccine Strategy and Immunisation Strategy.

Officials have drafted an initial series of key messages to support consistent, clear messaging for the communications campaign. The following draft key messages reflect initial planning and are a high-level representation of the types of messages that the Ministry intend to communicate to the public:

- Our COVID-19 response aims to protect our health and wellbeing from this virus, which is critical to support our economic recovery and enable us to re-open Aotearoa New Zealand's borders.
- Our overarching elimination strategy focuses on a range of control measures to stop transmission of COVID-19 in Aotearoa New Zealand, including border controls, robust case detection and surveillance, effective contact tracing and quarantine, and our strong community support of control measures.
- A safe and effective vaccine for COVID-19 is essential for our ability to control the virus in the long term, though there is still uncertainty around when we are going to get a vaccine and its effectiveness.
- Our COVID-19 Vaccine Strategy aims to ensure access to a safe and effective vaccine so we can implement an immunisation programme at the earliest possible time.
- Any vaccine will need to meet internationally accepted criteria for quality, safety and efficacy before Medsafe will approve its use here in Aotearoa New Zealand.
- An interagency COVID-19 Vaccine Strategy Task Force is overseeing implementation of the vaccine strategy, led by MBIE in partnership with the Ministry of Health and its regulatory agency Medsafe, PHARMAC, and the Ministry of Foreign Affairs and Trade.
- The Ministry of Health is designing a COVID-19 immunisation programme for roll-out when, a safe and effective vaccine becomes available.
- We're working closely with a range of stakeholders to make sure the widest possible range of needs, perspectives, concerns and advice are considered throughout the process.
- High uptake of the vaccine, which will be voluntary, is critical to achieve sufficient population immunity. Population immunity will help to protect all New Zealanders from COVID-19.
- Achieving equitable vaccination rates is a key measure of success, including protection for Māori, Pacific peoples and our most vulnerable population groups, such as older people, disabled people, health workers, essential workers and border staff.

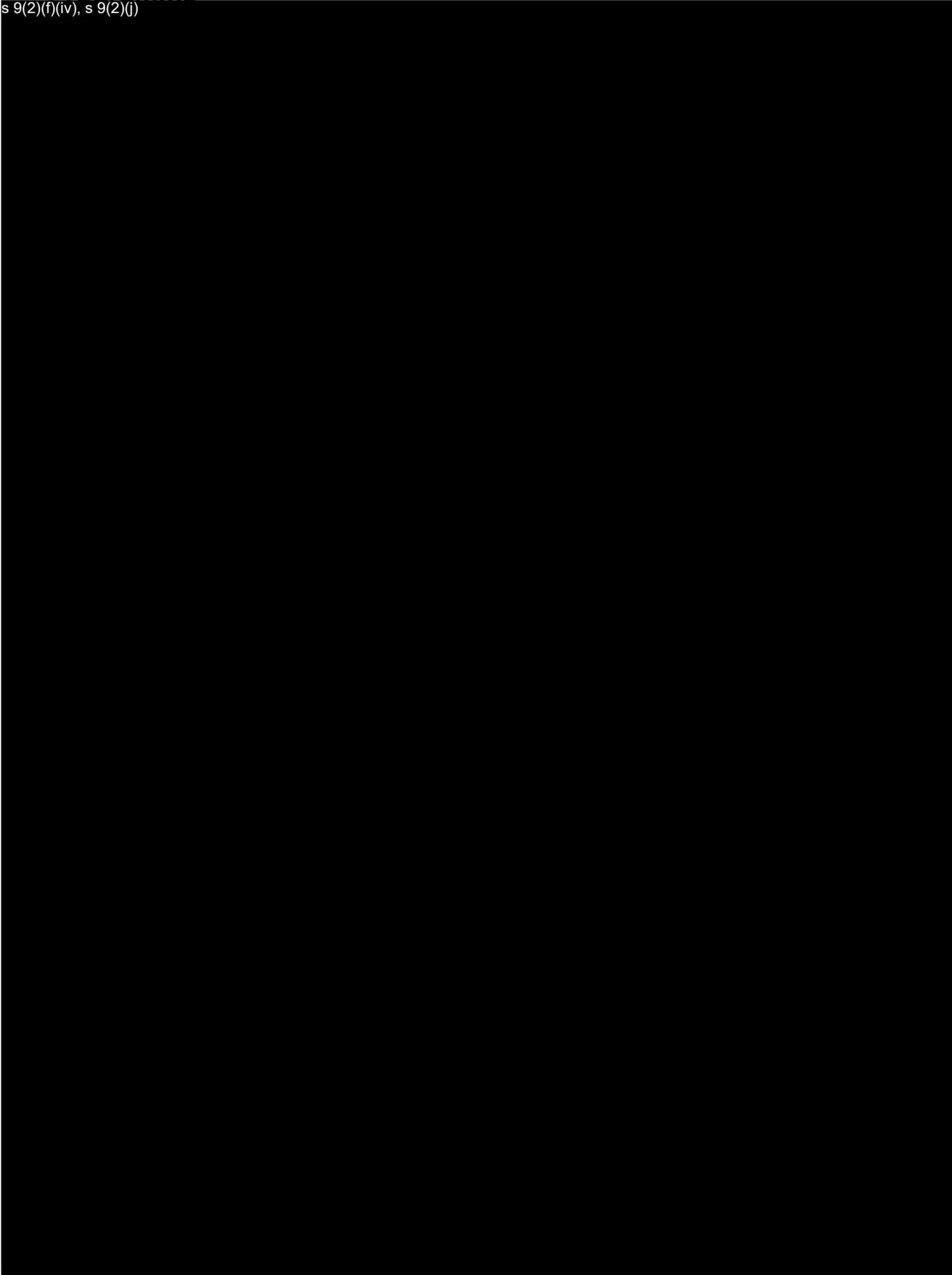
BUDGET SENSITIVE

- Upholding Te Tiriti o Waitangi principles and working in partnership with Māori is fundamental to this programme's success and protecting the unique whakapapa of Aotearoa New Zealand.
- We also have an important role in supporting our Pacific neighbours with access to a COVID-19 vaccine and their roll-out of an immunisation programme.
- We are planning a public health campaign to ensure we maintain strong community support for a COVID-19 vaccine, which is vital for a successful immunisation programme.
- While we do not know for certain when a vaccine will become available in New Zealand, the global effort to develop and trial a variety of vaccine candidates is well underway. New Zealand is entering bilateral advance purchase agreements (APAs) to purchase 750,000 courses of the Pfizer/BioNTech vaccine candidate and five million courses of the Janssen vaccine candidate (work is currently underway to finalise these agreements).
- New Zealand has invested in vaccine development, manufacture and advance purchasing agreements for vaccines.
- It is likely our immunisation programme will have a sequenced roll-out, depending on a range of factors, including vaccine suitability for different groups.
- Other public health measures and our strong border settings will continue to be an important part of our COVID-19 response and will not end immediately.
- We acknowledge there are multiple unknowns, including when a vaccine might be approved for use in New Zealand and who it will protect from the virus, but we will continue to provide clear and transparent updates on progress.
-

BUDGET SENSITIVE

Appendix Five: Detailed costings for the COVID-19 Immunisation Programme

s 9(2)(f)(iv), s 9(2)(j)



BUDGET SENSITIVE

s 9(2)(f)(iv), s 9(2)(j)



BUDGET SENSITIVE