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Office of the Minister for COVID-19 Response

Office of the Minister of Health

Office of the Associate Minister of Health

Cabinet

Pfizer recommendations for decision to use

Proposal

1 This paper provides you with advice on the use of the Pfizer COVID-19 vaccine in New Zealand.

Executive Summary

2 The Pfizer COVID-19 vaccine has been granted provisional consent by Medsafe and is now available for use as part of our COVID-19 Immunisation Programme.

3 It is recommended that we proceed with providing access as outlined in the Sequencing Framework. This recommendation has been assessed against the Decision to Use Framework and has been considered by the COVID-19 Vaccine Technical Advisory Group (CV TAG).

4 The CV TAG have noted that the vaccine is suitable for use in New Zealand for those 16 years of age and over, with some additional recommendations including:

4.1 ensuring adequate information provision, particularly around expected common side effects;

4.2 requiring a 30-minute observation period after the vaccine has been administered;

4.3 patients receiving specific therapies (listed in Appendix One) should not receive the vaccine;

4.4 that pregnant women are advised to discuss the risks and benefits of receiving the Pfizer vaccine; and

4.5 that it is suitable for use in lactating women.

5 There are no exclusions, or limitations in the advice of the CV TAG that would materially impact on the implementation of the Sequencing Framework and Immunisation Programme at this time.

6 Ministry of Health will provide further advice on use of the Pfizer vaccine and other vaccines in our portfolio as we progress to immunise wider population groups in the community.

Background

COVID-19 vaccines are critical in the continued response to COVID-19

7 In May 2020, Cabinet agreed to the COVID-19 Vaccine Strategy [CAB-20-MIN-0382 refers]. We are deliberately taking a portfolio approach to manage the risk of vaccine development failure and to support a successful COVID-19 Immunisation Programme [CAB-20-MIN-0508]. Through bilateral agreements, we have secured four vaccine candidates in our portfolio from three leading technology platforms.

8 We are expecting to purchase and take delivery of up to 15.79 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.

9 A vaccine portfolio provides 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.

10 We are providing advice on the Pfizer vaccine as it is now available for use, but without knowing if a future vaccine is going to be more suitable or effective. Future decisions to use will consider the opportunity cost against the risk of COVID-19 to New Zealanders at that time.

Cabinet has endorsed a Decision to Use Framework

11 In February 2021, Cabinet endorsed the Decision to Use Framework and updated Sequencing Framework to support best use of COVID-19 vaccines in our portfolio [CAB-21-MIN-0011 refers]. The Decision to Use Framework is attached as Appendix Two.

12 The Decision to Use Framework provides a robust process to inform decisions and optimise delivery of the COVID-19 Immunisation Programme and flow on portfolio implications.

13 It is expected that decisions will have to be revisited and adjusted as:

13.1 more vaccines become available for use;

13.2 more information becomes available on vaccine characteristics, and;

13.3 the situation in New Zealand and overseas changes.

Medsafe has granted provisional approval for the use of the Pfizer COVID-19 vaccine in New Zealand

14 As part of our portfolio, we have secured up to 750,000 courses of the Pfizer COVID-19 vaccine through an Advance Purchase Arrangements, and an additional 50,300 courses through the COVAX Facility.

15 Provisional consent for the Pfizer COVID-19 vaccine has been granted by Medsafe, the New Zealand Medicines and Medical Devices Safety Authority – the independent regulator under the Medicines Act 1981 (the Act).

16 Provisional consent allows conditions to be imposed on the vaccine. Provisional consent was included in the Medicines Act to allow New Zealand patients to have early access to medicines with a significant unmet clinical need.

17 Medsafe has granted provisional consent for the Pfizer COVID-19 vaccine with 58 conditions;

17.1 52 of the conditions relate to additional manufacturing data from Pfizer, to ensure that as the company upscales, they are manufacturing at a high quality and that all batches are consistent.

17.2 six conditions relate to additional clinical information, including regular updates from clinical trials and ensuring that Medsafe receive any information on safety concerns.

18 Provisional regulatory approval allows New Zealand to use the vaccine as part of the COVID-19 Immunisation Programme. The Pfizer vaccine is available for use for those 16 years of age or older.

19 There are also limitations on data provided, including:

19.1 The efficacy, safety and immunogenicity for immunocompromised individuals, including those receiving immunosuppressant therapy. This means that efficacy may be lower in immunosuppressed individuals.

19.2 Duration of protection, as this is still being determined by ongoing trials.

19.3 The safety and efficacy in children and adolescents aged less than 16 years of age has not been established.

19.4 Interactions with other medicines and co-administration with other vaccines.

The Pfizer vaccine is approved for all age groups except those under 16 years of age

20 Clinical trials have not yet included those under 16 years. While this is quite normal for this stage of clinical trials, it does mean that we do not have safety and efficacy evidence to support the use of the Pfizer vaccine for children and rangatahi aged less than 16 years. Given this, we recommend that the Pfizer vaccine is only used for people aged 16 years or older.

21 Once further paediatric trials are conducted, Medsafe will be able to consider broadening the approval conditions for the Pfizer vaccine.

22 Ministry of Health is developing clear messaging as part of its communication campaign, including why those under 16 years of age, will not be included in the initial phase of the immunisation programme.

Recommendations for use

23 This section outlines our recommended use for the Pfizer vaccine, now that it has been granted provisional consent. Recommendations are based on science and clinical advice to ensure that use of the vaccine will support a successful Immunisation Programme.

It is recommended that we proceed with using the Pfizer vaccine in line with the Sequencing Framework

24 The Ministry of Health recommends that COVID-19 Immunisation Programme proceed with the roll out of the Pfizer COVID-19 vaccine, which will initially include immunising Tier One of the Sequencing Framework (the Border and Managed Isolation and Quarantine workforces, along with their household contacts).

25 In alignment with Medsafe provisional approval and consultation with the CV TAG, there are no specific exclusions for the use of the vaccine that would materially impact on the Sequencing Framework or the Immunisation Programme delivery (Appendix One provides the recommendations of the CV TAG). The only initial impact is that, as anticipated, some household contacts who are under 16 years will be excluded. This will be reviewed once more safety information becomes available from future trials.

A number of the expert recommendations will be factored into the service design of the Immunisation Programme

26 Specific recommendations from the CV TAG that will be factored into the Immunisation Programme include:

26.1 ensuring adequate provision of information to recipients on expected side effects (e.g. fever, muscle pain, fatigue) and how to manage mild side effects, noting a high rate of common reactions is expected.

26.2 an observation period of 30 minutes following administration of the vaccine. This is a cautious approach in recognition that where an adverse reaction took place it mostly occurred within 30 minutes.

26.3 patients receiving some specific therapies are not recommended to receive the Pfizer vaccine (see Appendix One).

26.4 that the Pfizer vaccine is suitable for use in pregnancy, however it is advised that pregnant woman discuss the risks and benefits with a health professional.

26.5 that the Pfizer vaccine is suitable for use in lactating women.

27 The Ministry of Health will continue to engage the CV TAG to ensure that we receive timely science and clinical advice and updates that would impact on the Immunisation Programme.

We will provide further advice on the use of the Pfizer vaccine before we start immunising Tier 3 at scale

28 We will provide further advice on the use of the Pfizer vaccine, alongside the other vaccines in our portfolio, before we start immunising people identified in Tier Three at scale (Tier Three includes people in the community most at risk of serious illness and the workforces supporting them).

29 s 9(2)(b)(ii) [redacted]

30 There are expected to be several options as to how we proceed and utilise the portfolio going forward.

31 Subsequent advice on the use of additional COVID-19 vaccines will consider the opportunity cost of using that particular vaccine in the context of the portfolio and the risk of COVID-19 to New Zealanders at that time.

32 It is possible that the Ministry of Health will recommend not to proceed with vaccines that are available for use, in favour of other vaccines in our portfolio that might be arriving at later date, but are likely to have better outcomes for the Immunisation Programme.

33 The Ministry of Health will advise on how we ensure that any doses not used in New Zealand or Polynesia are offered to other jurisdictions where possible. This could include sharing these doses bilaterally or through the COVAX Facility to ensure they are put to use.

New Zealand is supporting equitable access to COVID-19 vaccines for our Pacific partners

34 New Zealand continues to play a role internationally and specifically with the Pacific countries participating in the Polynesian Health Corridors programme, including the Cook Islands, Niue, Tokelau, Samoa, Tonga and Tuvalu will be given access to the New Zealand vaccine portfolio.

35 We expect that as part of the next decision window and assessment of vaccines in our portfolio that consideration will be given to the allocation of vaccines for the Polynesian Health Corridors programme.

36 There is a need to prioritise access for these countries. A COVID-19 outbreak and rapid spread of the virus in Polynesia, particularly with the new COVID-19 variants, would likely have severe health consequences and place great pressure on already fragile health systems.

Implementation

37 The COVID-19 Immunisation Programme is ready to deliver COVID-19 vaccines to Tier One from mid-February 2021 at the earliest. It is expected that delivery will ramp

up as supplies of the Pfizer vaccine allows. The initial service design is focused on providing access to the vaccine through workplaces and community pop ups.

38 Cabinet previously noted, the anticipated timelines for the first four days following arrival in New Zealand of the first shipment of the Pfizer vaccine [CAB-21-MIN-0011 refers]:

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
4	Vaccination site receive vaccines and consumables **Vaccination start**	2-8 degrees

Financial Implications

39 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.

Population Implications

40 The potential benefit offered by the Pfizer candidate and a key reason for its inclusion in our portfolio, was the expected timeliness of delivery. Early access but limited supply means we can use it to protect groups most at risk of contracting and spreading COVID-19, which is supported by the World Health Organisation's framework for allocation and prioritisation of COVID-19 vaccination.

41 Access to COVID-19 vaccines will be given to all New Zealanders over time. While supply of the vaccine is constrained, we are utilising the Sequencing Framework to guide decision making in relation to rollout, which takes into consideration the scenario New Zealand is in, along with the characteristics of the population. Broadly this means that populations are being provided access based on their risk to experiencing harm from COVID-19, with the intention of promoting equitable outcomes.

42 As further vaccine doses become available, and later decisions to use are made, access will eventually be opened to the whole population of New Zealand. As such, the initial focus will be on the personal protection of individuals and their whānau, which will then develop into protection of the New Zealand population.

43 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

44 Vaccines are being prioritised for certain people while 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.

45 The differential treatment of population groups, such as vaccines being made available earlier to certain persons or groups is based on the impact to the wider population, the particular risk faced by these people, as well as promoting equitable outcomes.

46 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

47 The Ministry of Health has consulted with the Ministries of Foreign Affairs and Trade, Business, Innovation and Employment, and the Treasury. The Department of the Prime Minister and Cabinet has been informed

Communications

48 It is anticipated that Ministers will publicly announce:

48.1 the decision to use the Pfizer vaccine in line with the previously agreed Sequencing Framework

48.2 the impact of the advice from the Covid-19 Vaccine Technical Advisory Group, in particular that children and rangatahi under 16 years will not be able to receive the Pfizer vaccine at this time.

49 The Ministry has already started providing key message to the workforces outlined in Tier One of the Sequencing Framework, and has a number of engagements planned to enable the target populations to ask questions and get reliable information about the vaccine.

50 The Ministry will also be updating its public information to reflect the new guidance. Proactive Release

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

Recommendations

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

1.1 note that the Pfizer COVID-19 vaccine has been granted provisional consent by Medsafe and is now available for use as part of our COVID-19 Immunisation Programme.

1.2 note that the Ministry of Health has formed a COVID-19 Vaccine Expert Advisory Group, to provide science and technical advice on the use of COVID-19 vaccines.

1.3 note that the COVID-19 Vaccine Expert Advisory Group has provided advice to the Director General on the use of the Pfizer vaccine.

1.4 Note that the Pfizer vaccine is suitable for use in New Zealand for those 16 years of age and over, with some additional recommendations:

1.4.1 ensuring adequate information provision, particularly around expected common side effects;

1.4.2 requiring a 30-minute observation period after the vaccine has been administered;

1.4.3 patients receiving specific therapies (listed in Appendix Two) should not receive the vaccine;

1.4.4 that pregnant women are advised to discuss the risks and benefits of receiving the Pfizer vaccine; and

1.4.5 that it is suitable for use in lactating women.

1.5 note that there are no exclusions, or limitations in the advice of the COVID-19-Vaccine Expert Advisory Group that would materially impact on the implementation of the Sequencing Framework and Immunisation Programme at this time.

1.6 agree that we proceed with using the Pfizer vaccine as per the Sequencing Framework.

1.7 note that we will seek further decisions on the use of the Pfizer vaccine and other vaccines in our portfolio as they become available.

1.8 note that subsequent advice on the decision to use additional COVID-19 vaccines advice will consider the opportunity cost of using a particular vaccine in the context of the portfolio, and the significant risk of COVID-19 to New Zealand.

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: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

1 Following Medsafe's provisional approval of the Pfizer mRNA COVID-19 vaccine (Comirnaty, BNT162b2) for people 16 years and over on 3 February 2021, the COVID-19 Vaccine Technical Advisory Group (CV TAG) met on 4 February 2021 to provide the science and technical assessment of the Pfizer mRNA COVID-19 vaccine, including who is to receive the vaccine.

2 The CV TAG has completed a science and technical assessment of the Pfizer mRNA COVID-19 vaccine, in order to provide these recommendations.

3 The CV TAG recommends that:

- 3.1 the Pfizer mRNA COVID-19 vaccine is suitable for use in New Zealand for all people 16 years of age and over, including for people over 65 years;
- 3.2 the Pfizer mRNA COVID-19 vaccine is suitable for use in immunocompromised individuals. However, patients receiving the following therapies should get advice from their specialist before receiving the Pfizer mRNA COVID-19 vaccine: pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), atezolizumab (Tecentriq);
- 3.3 the Pfizer mRNA COVID-19 vaccine is suitable for use in pregnancy. However, as there is currently no data on outcomes in pregnant women, they should discuss the risks and benefits of receiving the Pfizer mRNA COVID-19 vaccine with a health professional;
- 3.4 the Pfizer mRNA COVID-19 vaccine is suitable for use in lactating women;
- 3.5 people with a history of anaphylaxis to any previous Pfizer mRNA COVID-19 vaccine or any component of the vaccine should not receive a Pfizer mRNA COVID-19 vaccine;
- 3.6 because of the rare potential for severe allergic reactions (anaphylaxis), it is recommended that all subjects be observed for 30 minutes after the vaccine has been administered;
- 3.7 people with a history of any immediate allergic reaction to other vaccines or any products may be vaccinated but this should be done in a health care setting, where in the unlikely event of a reaction, it can be immediately treated with adrenaline.

4 The group noted that given the relatively high prevalence of common side effects with the Pfizer mRNA COVID-19 vaccine, it is important that all recipients should receive information about expected responses (e.g., fever, muscle pain, fatigue), how to manage these (e.g., analgesia) and who to call for advice if these reactions become problematic. Such reactions are more frequent after administration of the second dose (patient information may need to be adjusted).

Appendix Two: Decision Framework