BRIEFING

Purchase of COVID-19 vaccines from Janssen Pharmaceutica NV

Date:	13 November 2020	**Priority:**	Urgent
Security classification:	Sensitive	**Tracking number:**	2021-1195

Action sought		
	Action sought	**Deadline**
Rt Hon Jacinda Ardern **Prime Minister** Hon Grant Robertson **Minister of Finance** Hon Dr Megan Woods **Minister of Research, Science and Innovation** Hon Andrew Little **Minister of Health**	**Agree** to terms that will form the basis of an advance purchase agreement with Janssen Pharmaceutica NV for five million courses of a vaccine against COVID-19.	18 November 2020

Contact for telephone discussion (if required)

Name	**Position**	**Telephone**	**1st contact**
Poppy Haynes	Manager, COVID-19 Vaccine Purchase, MBIE	9(2)(a)	✓
Maree Roberts	Deputy Director-General, System Strategy & Policy, MoH	9(2)(a)	
Bhagee Ramanathan	Principal Policy Advisor, MBIE	9(2)(a)	

The following departments/agencies have been consulted

PHARMAC, MBIE, MoH, MFAT, Treasury, DPMC

Minister's office to complete:

- ☐ Approved
- ☐ Noted
- ☐ Seen
- ☐ See Minister's Notes
- ☐ Declined
- ☐ Needs change
- ☐ Overtaken by Events
- ☐ Withdrawn

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

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Purpose

To seek approval to terms that will form the basis of an advance purchase agreement with Janssen Pharmaceutica NV (Janssen) to purchase five million courses of a potential vaccine against COVID-19. The vaccines are expected to be delivered in the third quarter of 2021 and in 2022 (subject to successful development and regulatory approval).

Executive summary

Background

Our ability to recover from the COVID-19 pandemic and relax other public health controls relies on the availability of safe and effective COVID-19 vaccines. The global demand for COVID-19 vaccines continues to be high, and there is heavily constrained capacity to manufacture vaccines.

In response to these challenges the Government:

- approved the Vaccine Strategy [CAB-20-MIN-0229.01] with the objective of ensuring access to a safe and effective vaccine
- established a tagged contingency of up to $600 million [CAB-20-MIN-382] for purposes including advance purchase arrangements of potential COVID-19 vaccines and delegated purchase decisions to the Prime Minister, the Minister of Finance, the Minister of Research, Science and Innovation and the Minister of Health (Joint Ministers)
- through Joint Ministers, agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (briefing MBIE 2021–0662 refers).

The purchasing strategy aims to pre-purchase a portfolio of potential vaccines through advance purchase agreements (APAs) at a stage where the candidates still carry a risk of failure. We have early information about their performance, information about manufacturing processes and plans, and other countries' decisions to enter into APAs.

Money spent on APAs may be lost if the development is unsuccessful, if the candidate is found to be unsuitable for deployment as part of the Government's preferred immunisation strategy, or if the supply is in excess of what is required under that strategy and cannot be on-sold. In the current global context, this is the cost of attempting to secure supply of vaccines that are still being developed.

By the end of the year we will recommend the purchase of four vaccines to create a 'core portfolio'

Of the vaccine candidates under development globally, the Vaccine Taskforce has prioritised concluding negotiations with four suppliers by the end of the year: Pfizer, AstraZeneca, Janssen and Novavax. Securing these APAs will give us a promising 'core portfolio' that is expected to meet the objectives of the Vaccine Strategy. Joint Ministers have already agreed to purchase 750,000 courses of Pfizer Inc.'s COVID-19 vaccine candidate (briefing MBIE 2021-0996 refers). Janssen's offer is an opportunity to purchase a potentially single-dose vaccine in sufficient

numbers to provide broad population cover. We hope to conclude negotiations with AstraZeneca and Novavax within the next fortnight.

The offers are time-limited, and it is imperative that heads of terms and subsequent APAs are concluded promptly in order to secure the vaccines for New Zealand from global allocations.

One or two additional high-volume purchases may be necessary to give the portfolio sufficient diversity to provide a high degree of confidence that it will achieve the Vaccine Strategy's objectives.

Overall, this vaccine appears to meet the purchase framework criteria

The purchase framework considers vaccine performance, availability and access, and contribution to portfolio balance and strategic fit. We have taken advice from Bell Gully, and an independent science advisory panel, during the negotiation. PHARMAC has also been involved. The negotiated offer is in the form of a non-binding term sheet and is attached in Annex One.

We recommend agreeing to the Janssen offer because:

- Janssen, in conjunction with its parent company Johnson & Johnson, has a proven track record in developing, manufacturing and delivering a product that meets New Zealand's quality standards.
- subject to clinical trials, it is the only potential single-dose vaccine in our target group, and could provide broad population cover within the timeframes required to implement the immunisation programme planned for 2021 and 2022.
- other countries applying similar purchasing frameworks to us have APAs with Janssen, and our own purchase framework analysis supports the decision to purchase the candidate.
- it will increase the technology diversity of our portfolio, and is likely to be among the group of earliest available vaccines for regulatory review and use in New Zealand.
- it may be relatively easy to deliver, despite some logistical challenges. This could be of particular value for delivery in the Pacific.

At around 9(2)(ba)(i), 9(2)(ba)(ii) drawing-down 9(2)(ba)(i),9(2)(ba)(ii) We recommend from the "Minimising the health impacts of COVID-19 – Tagged Operating Contingency" to fund the purchase of the vaccines and address foreign exchange risk. 9(2)(ba)(i), 9(2)(ba)(ii)

Regulatory approval

Safety and effectiveness are necessary conditions that will need to be satisfied before COVID-19 vaccines are available to be deployed. We understand from Medsafe that Janssen have provided pre-submission information and that Janssen is aware of the need to engage with the Environmental Protection Authority.

Next steps

Subject to your agreement to the recommendations in this briefing the Director-General of Health, on behalf of the New Zealand Government, will sign the non-binding term sheet attached at Annex One. The term sheet contains the key terms for the APA and confirms both parties' intention to negotiate an APA within four weeks of executing the term sheet. Your approval will be sought for the terms of the APA. That approval will be subject to the Minister of Finance's agreement to the terms of an indemnity for Janssen.

Subject to your agreement to agree to purchase terms with Janssen, we will work with them and with Ministers' offices to plan communications and publicity opportunities, including an announcement in support of the agreement.

Recommended action

The Ministry of Business, Innovation and Employment, and the Ministry of Health recommend that you:

a) **Note**, an unprecedented global health crisis continues and the New Zealand population remains almost totally susceptible to COVID-19 due to our successful elimination strategy.

Noted

b) **Note**, the global demand for COVID-19 vaccines continues to be high, and capacity to manufacture successful vaccine candidates is heavily constrained worldwide, and this situation is likely to continue for some time. Comparator countries are pre-purchasing multiple COVID-19 vaccine candidates to mitigate the risk of development failure.

Noted

c) **Note**, in May Cabinet approved the COVID-19 Vaccine Strategy [CAB-20-MIN-0229.01] with the objective of ensuring access to a safe and effective vaccine to implement the Government's preferred immunisation strategy at the earliest possible time.

Noted

d) **Note**, in August Cabinet established a tagged contingency of up to $600 million [CAB-20-MIN—382] for purposes including the advance purchase arrangements of potential COVID-19 vaccines, Cabinet also delegated purchase decisions to Joint Ministers.

Noted

e) **Note**, in September Joint Ministers agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (briefing MBIE 2021 – 0662 refers).

Noted

f) **Note**, we have been assessing vaccine candidates prioritised by the Vaccine Taskforce against the purchase framework.

Noted

g) **Note**, you have agreed to accept an offer from Pfizer for the purchase of 750,000 courses of an mRNA vaccine candidate for delivery early next year (briefing MBIE 2021-0996 refers).

Noted

h) **Note**, there is an opportunity to purchase two million courses of Janssen Pharmaceutica NV's vaccine candidate for delivery in the third quarter of 2021, with an option to purchase three million courses for delivery in 2022.

Noted

i) **Note**, the negotiations for this purchase opportunity have been carried out with advice from legal and science experts. We have achieved a number of important concessions such as increasing the number of vaccine courses to provide wide population cover for New Zealand, and the ability to resell or pass-on vaccines to Realm and other Polynesian countries.

Noted

j) **Agree**, to terms that will form the basis of an advance purchase agreement to purchase two million courses and an option to purchase an additional three million courses of Janssen Pharmaceutica NV's COVID-19 vaccine candidate (the terms are attached in Annex One), 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

Agree / Disagree

k) **Agree**, if you agree to the recommendation in j), the Director-General of Health sign the term sheet on behalf of the New Zealand Government to give effect to that decision.

Agree / Disagree

l) **Agree**, if you agree to the recommendation in j), to draw down 9(2)(ba)(i), 9(2)(ba)(ii) from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' to purchase the Janssen vaccine candidate.

Agree / Disagree

m) **Approve**, if you agree to the recommendation in l), the following changes to appropriations to provide for the decision in recommendation l) above, with a corresponding impact on the operating balance and net core Crown debt:

	$m - increase/(decrease)				
Vote Health **Minister of Health**	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**2024/25 & Outyears**
Non-Departmental Output Expenses: Minimising the Health Impacts of COVID-19	9(2)(ba)(i), 9(2)(ba)(ii) [redacted]		-	-	-
Total Operating			-	-	-

Approve/ Not approve

n) **Agree**, that the changes to appropriations for 2020/21 above be included in the 2020/21 Supplementary Estimates and that, in the interim, the increase be met from Imprest Supply.

Agree / Disagree

o) **Note**, we will seek your approval for the conclusion of a definitive agreement with Janssen. That approval will be subject to the Minister of Finance's agreement to grant an indemnity to Janssen.

Noted

p) **Note**, that Treasury officials will seek agreement of the Minister of Finance to the terms of an indemnity for Janssen at the time we seek our approval for the conclusion of a definitive agreement.

Noted

q) **Note**, other negotiations for the advance purchase of COVID-19 vaccines are underway, and two are expected to be concluded in the next fortnight.

Noted

r) The Prime Minister **forward** a copy of this briefing to the Minister for COVID-19 Response and to the Minister of Foreign Affairs.

Rt Hon Jacinda Ardern
Prime Minister
...../...../.....

Hon Grant Robertson
Minister of Finance
...../...../.....

Hon Dr Megan Woods
Minister of Research, Science, Innovation
...../...../.....

Hon Andrew Little
Minister of Health
...../...../.....

Maree Roberts
Deputy Director-General, Ministry of Health
Ministry of Health
..... / ..... / .....

Dr Peter Crabtree
GM, Science, Innovation, International, MBIE
..... / ..... / .....

Background

Global demand for vaccines remains high

1. An unprecedented health crisis continues worldwide, and New Zealand's population remains entirely susceptible to COVID-19 due to our successful elimination strategy.

2. Our ability to recover from the COVID-19 pandemic and relax other public health controls relies on the availability of safe and effective COVID-19 vaccines. The global demand for COVID-19 vaccines continues to be high, and capacity to manufacture successful vaccine candidates is heavily constrained worldwide. This is expected to be the case for some time.

Ministers have previously agreed to a COVID-19 vaccine purchasing strategy and a framework to guide purchase decisions

3. In May, Cabinet agreed a purchasing strategy to support acquisition of COVID-19 vaccines [CAB 20-MIN-0382]. A portfolio approach is intended to manage the risk of failed vaccine development and provide a range of effective vaccines to choose from for early deployment as part of New Zealand's immunisation strategy. This improves the chances of acquiring one or more vaccines that are safe and sufficiently effective for use in New Zealand. The construction of the portfolio therefore requires the selection of vaccine candidates that ensure diversity across technology platforms, suppliers, and timeframes, that address equitable population coverage, and include vaccines suitable for use in the Realm of New Zealand and other Polynesian countries.

4. In August, Cabinet established a tagged contingency of up to $600 million [CAB-20-MIN-382] in order to finance advance purchase agreements (APAs) of potential COVID-19 vaccines and to meet additional early costs for Government's immunisation programme. Cabinet delegated purchase decisions to the Prime Minister, the Minister of Finance, the Minister of Research, Science and Innovation and the Minister of Health (Joint Ministers).

5. Joint Ministers have agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (briefing MBIE 2021 – 0662 refers). The application of the framework criteria is intended to ensure that APAs align with New Zealand's overall objectives for responding to COVID-19 and recognise that our decisions on advance purchasing will be made on the basis of early-stage information.

6. Once concluded, APAs will commit New Zealand to the purchase of vaccines, conditional on successful clinical trials of the vaccine candidate and regulatory approval in New Zealand. Decisions to be taken later, including whether to use these vaccines in New Zealand, or whether to pass on any vaccines to the Pacific, will depend on their suitability for deployment, either as part of New Zealand's immunisation strategy, or in the Pacific.

7. Discussion with international counterparts and media announcements indicate a number of like-minded countries have reserved large quantities of a number of vaccine candidates through APAs in order to mitigate the risk that vaccine candidates could fail.

By the end of the year we will recommend the purchase of four vaccines to create a 'core portfolio'

8. From the vaccine candidates globally under development we have progressed negotiations with eight targeted vaccine suppliers. The COVID-19 Vaccine Strategy Taskforce have prioritised concluding negotiations with four of those suppliers by the end of the year: Pfizer, AstraZeneca, Janssen and Novavax. Together these APAs will give us a promising 'core portfolio' in line with what other advanced economies have purchased.

9. Each candidate would contribute to the portfolio in a complementary way – the point of difference for the Janssen candidate is that it is potentially a single-dose vaccine and is therefore more straightforward to deliver than two-dose candidates. Available information

about these candidates is broadly promising and we do not have any major concerns from early clinical trial information. The table in Annex Two summarises the population coverage being sought, price and delivery times being negotiated for the four highest priority target vaccine candidates.

10. In prioritising and advancing these four negotiations we have relied on commercial, legal and expert scientific advice. We have assessed these offers against the vaccine purchase framework (see discussion from paragraph 24), and our negotiation priorities. We also received advice and endorsement from portfolio managers on the overall approach to the construction of our vaccine portfolio.

11. Last month Joint Ministers agreed to purchase 750,000 courses of vaccines from Pfizer Inc. (briefing MBIE 2021-0996 refers). Janssen's offer is outlined below. Negotiations are at an advanced stage with AstraZeneca and Novavax and we hope to advise you on terms for purchases within the next fortnight.

12. The offers are time-limited, and it is imperative that heads of terms and subsequent APAs are concluded promptly because New Zealand's vaccine allocations are held temporarily from global allocations. We will therefore advise you on purchase decisions as each negotiation concludes. There is limited control over the sequence of purchases.

13. We have confidence that the probable portfolio would deliver sufficient volumes to New Zealand within our required timeframes. However, at this stage there is uncertainty about how safe, efficacious, and widely useable the portfolio's candidates will be (especially for at risk groups). One or two additional high-volume purchases may therefore be necessary to give the portfolio sufficient diversity. This would give a high degree of confidence that the immunisation programme has sufficient options available to ensure it will achieve the Vaccine Strategy's objectives.

The purchase from Janssen could provide sufficient COVID-19 vaccines for broad population cover

14. Janssen has offered New Zealand two million courses of its vaccine candidate (known as Ad26.COV2.S) for delivery in the third quarter of 2021 and an option to purchase a further three million courses for delivery in 2022. The candidate is an inactivated viral vector vaccine.[1] It will cost 9(2)(ba)(i), 9(2)(ba)(ii) If successfully developed and delivered this vaccine purchase 9(2)(ba)(i), 9(2)(ba)(ii)

15. Depending on clinical trial results, the supplier expects the vaccine to consist of a single dose administered by injection, though they will investigate a two-dose regimen for ongoing immunity following the pandemic period. This is a significant advantage, and point of difference of this vaccine.

16. Non-replicating viral vector vaccines are a relatively new technology. The human adenovirus vector used in this particular viral vector vaccine (branded by Janssen as "Advac") has been used in the development of vaccines for emergency use (e.g. against HIV, Zika, and Ebola)

[1] The candidate is a non-replicating viral vaccine, which works by carrying DNA into human cells that then produce vaccine antigen. The antigen provokes an immune response to the disease.

[2] 9(2)(ba)(i), 9(2)(ba)(ii) There is a foreign exchange risk and the Treasury have recommended including headroom 9(2)(ba)(i), 9(2)(ba)(ii) to address that risk. Therefore the amount required to be set aside for the purchase 9(2)(ba)(i), 9(2)(ba)(ii)

without safety signals being detected. However, there are no licensed vaccines using this platform.

17. Similarly to other vaccine candidate targets, negotiations with Janssen have been prioritised because there is high confidence in the ability of the supplier to develop, manufacture and deliver a COVID-19 vaccine to required quality standards.

18. While there are inherent risks to the delivery time of all vaccine candidates, this vaccine has the potential to be one of the small group that are likely to be available within the timeframe needed to implement an immunisation programme in New Zealand over 2021 and 2022.

19. The Ministry of Health is developing an approach to COVID-19 immunisation, which will determine how the vaccine will be used to support the Government's overall COVID-19 elimination strategy and equity considerations.

20. The offer from Janssen is made in the form of a non-binding term sheet. This appears to be Janssen's global approach. It contains the general terms of the arrangement and confirms both parties' intention to negotiate the APA within four weeks of signing the term sheet. The APA is likely to contain other terms consistent with the proposed terms and typically found in pharmaceutical supply and funding agreements, including terms in past agreements used by PHARMAC.

21. Upon conclusion of the APA the following payments will be due:

- 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]
- 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

22. The non-binding term sheet must be executed before negotiations can commence on the APA.

We recommend purchasing the Janssen candidate

23. We believe there is a strong rationale to sign the term sheet because:

- Subject to successful clinical trials, this vaccine is likely to be the only single-dose vaccine available in the timeframe suitable for the immunisation programme. A single dose regimen is significantly more straightforward to administer than a two-dose regimen and avoids the risk of people failing to present for their second dose. It is being offered in quantities sufficient for wide population use.
- Janssen, along with its parent company Johnson & Johnson, have a very strong track record in producing safe and efficacious pharmaceutical products for use globally and in New Zealand. This gives us confidence in their ability to develop, manufacture and deliver a vaccine to prescribed standards.
- We have negotiated terms that we believe are satisfactory, and are in line with global trends for COVID-19 vaccine advance purchase arrangements.
- It is one of the most purchased vaccine candidates. Together, the USA, the UK, Canada and the EU have advance purchase arrangements with Janssen for around 570 million courses of this vaccine candidate.[3] Those countries have used similar

[3] The USA has purchased 100 million courses, the UK has purchased 30 million courses, Canada has purchased 30 million courses, and the EU has purchased 400 million courses.

frameworks to ours, using their experts to interrogate the early science results, trial designs and manufacturing programmes.

- The Janssen candidate will increase the technology diversity of our portfolio, which does not yet contain a viral vector vaccine. The other two candidates are a viral vector vaccine and a protein sub-unit vaccine.[4]
- Being a potentially single-dose regimen this vaccine candidate could be better suited for use in the Pacific or for harder-to-reach populations than other candidates.
- The major disadvantage of this vaccine is that its shelf-life is currently measured to be three months. This may extend once further testing has been completed.

Overall, this vaccine appears to meet the purchase framework criteria

24. The vaccine purchase framework is outlined in Annex Three. It considers expected vaccine performance, expected availability and access, and contribution to portfolio balance and strategic approach. Vaccine performance considers criteria such as safety profile, effectiveness and ease of distribution across the population as a whole and to particular population groups. Availability and access considers factors such as confidence in production, contractual terms and geopolitical dynamics and international risks. In advance of full vaccine development and regulatory approval and in the absence of final data, the framework uses proxies to help inform choices.

25. We took a multi-agency approach in negotiations to strengthen the level of interrogation. We have taken advice from Bell Gully, as well as from an independent scientific and clinical review panel, to help inform our analysis of the offer and information about the vaccine candidate, the developer and the supplier. Overall, we consider that the criteria in the framework have been met to a satisfactory level. That analysis is discussed below, with further detail attached as Annex Four.

Application of vaccine purchase framework criteria

	Criteria	Importance	Assessment of criteria	Level of satisfaction of criteria
Performance	**Safety profile and effectiveness**	Critical	As confident as we can be from early information	✓ ✓ ✓ *
	Ease of distribution	High	Some logistical complexities, but generally in line with norms	✓ ✓ ✓
	APAs with other countries	High	Large number of APAs concluded	✓ ✓ ✓
Accessibility	**Production**	Critical	Confidence in planned production	✓ ✓ ✓
	Contracting	High	Satisfactory contractual terms negotiated	✓ ✓ ✓
	International risk	High	International risk is low-medium	✓ ✓
	Comparable price offered to others	High	International price achieved	✓ ✓ ✓

[4] Protein-based subunit vaccines present an antigen to the immune system using an isolated protein of the pathogen.

Portfolio	**Portfolio fit**	Critical	Good fit with portfolio strategy	✓ ✓ ✓

Key: ✓ ✓ ✓ high satisfaction of criteria; ✓ ✓ moderate satisfaction of criteria; ✓ satisfaction of criteria; • criteria not met.

* From limited early data. It will be essential to see more data from human trials for this candidate before drawing conclusions about its safety, immunogenicity and efficacy.

The candidates shows some promise in terms of performance, but only early stage data is available now

26. As is normal at this stage in the clinical trials, limited information is available about the vaccine candidate's performance. Commentary from the science review panel provided on 18 October 2020 is attached as Annex Five. We will continue to monitor new information about safety and efficacy as clinical trial data becomes available. Specifically, in relation to two criteria which contribute to vaccine performance this candidate shows some promise:

- Safety – Previous vaccines based on this platform show low to no risk of disease enhancement. They have also been well tolerated over a large demographic range (elderly, HIV+, pregnant, children over 4 months). There are not likely to be particular issues with trial design in terms of safety (other than relatively short follow up periods observed in all COVID-19 vaccine trials to date).

- Human trials are still in early stages, so few safety data are available. It will be essential to see full phase I/II data before reaching any conclusions about safety, but interim analyses show a relatively high proportion of 18-55 year old participants experienced temporary side effects.

- As with other COVID-19 candidate vaccines, there is the potential for safety issues including disease enhancement after vaccination. By the time a decision is likely to be taken in New Zealand on whether or not to use a vaccine, additional data about safety are likely to be available from human trials.

- Effectiveness –The animal efficacy data for this vaccine are impressive, but clinical data is necessary to determine if that will translate to efficacy in humans. The developer appears to be using sensible approaches, but some information is not yet available.

- Only early human immunogenicity data are available which shows virus neutralising antibody in vaccines to be at a somewhat lower concentration than in those who have recovered from the disease.

- The vector is human adenovirus based, so there is the theoretical potential that prior exposure to adenovirus may reduce the immune response in humans.

Deployment requirements are within general expectations for COVID-19 vaccines

27. You have agreed to draw down $66.3 million from the tagged contingency to urgently purchase critical resources for the immunisation programme, including resources to support cold chain capacity around New Zealand, of the type needed to deploy this vaccine candidate (briefing MoH 20201744 refers).

The Janssen candidate is one of the two most purchased vaccine candidates in our target group

28. An important proxy indicator of vaccine performance is the extent to which APAs have been concluded with other countries who have greater resources to vet candidates and use the same purchase frameworks. Janssen has concluded arrangements with the USA, the UK, Canada and the EU for the sale of around 570 million courses of its vaccine candidate.

If the clinical trials are successful, there is strong confidence that Janssen will be able to supply the vaccine to New Zealand

29. Janssen has a proven track record for their ability to manufacture and deliver a product that meets New Zealand's quality standards. It does not appear that the supplier is selling above their capacity to deliver, and there are no current concerns about the reliability of supply chains or manufacturing capability from their planned manufacturing sites, which, so far are in the USA, Italy and India. Janssen has indicated that it intends to manufacture the drug substance and drug product for New Zealand at BioE in Hyderabad, India. 6(a) [redacted]

Delivery schedules are not certain, deliveries may be delayed and there is no guarantee of a vaccine

30. The terms do not create fixed delivery obligations. This is common to all candidates because vaccines are not yet registered, trials are ongoing, and manufacturing scale-up has not been completed. Indicative delivery schedules have been agreed, and are earlier than we were initially offered. Factors that will have an impact on the eventual delivery schedule include the supplier's ability to produce the information required by Medsafe.

The vaccine candidate is reasonably priced and is not expected to have significant additional administration costs

31. The supplier has made a commitment to making their vaccine candidate available globally on a not-for-profit basis during the emergency pandemic response period. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] Janssen will probably transition to commercial pricing at the end of the emergency pandemic period. Distribution and deployment costs are likely to be within the normal range for COVID-19 vaccines.

The vaccine would play an important role in the portfolio because it has the potential to be delivered as a single dose and could provide wide population cover

32. Janssen's candidate offers a vaccine that could potentially provide the core of an immunisation programme. Its single-dose format offers a potentially simpler deployment model than other vaccines under consideration. Janssen's trial design is broad in its coverage of different population cohorts, meaning that there is a realistic prospect of it being delivered widely across the New Zealand population, including hard-to-reach and at-risk population groups such as the elderly and those with chronic medical conditions.

33. The main weakness of the Janssen candidate from a portfolio perspective is that the first delivery will not occur before the third quarter of 2021. Other candidates prioritised for broad population access are currently proposing to begin deliveries in the middle of 2021, and the third quarter of 2021. The limited shelf-life of the Janssen vaccine and constrained storage facilities have the potential to limit its use in the Pacific despite its advantageous potentially single-dose format. We are hopeful that as more data is collected, the recommended shelf-life of the vaccine will improve.

34. At this point we would not recommend exercising the option to purchase the additional three million courses because further relevant information may become available before this decision is necessary.

9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

35. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

Opportunities for local manufacture of vaccines was sought as a means of mitigating supply risks

36. Janssen has ruled out any manufacturing arrangements in New Zealand for vaccines produced for this purchase arrangement.

37. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

Janssen is in negotiation with the COVAX Facility

38. New Zealand has entered into a binding commitment for the Optional Purchase Arrangement available through the COVAX Facility (briefing MBIE-2021-0858 refers). The COVAX Facility anticipates commencing delivery of vaccines as early as the first quarter of 2021. It hopes to procure sufficient doses for twenty percent of participants' populations by the end of 2021. Therefore, the usefulness of exercising an option for Janssen vaccines (should they become available through the Facility) will depend largely on expected delivery times and immunisation planning.

Commercial considerations

39. We have taken legal and commercial advice from Bell Gully and others during the negotiation of terms with Janssen. PHARMAC has also been involved in the negotiations. We consider that a good outcome has been achieved. Important concessions, such as increasing the number of vaccines offered, and having the ability to pass-on or resell the vaccine under particular circumstances, have been achieved. Mutually acceptable outcomes have been achieved where New Zealand had to make concessions, such as the terms of the indemnity sought by Janssen, which is discussed below.

40. The terms proposed are in line with the negotiating priorities agreed with the Vaccine Taskforce, and we understand they are in line with commercial expectations, with the exception of the indemnity. An outline of how the terms compare to negotiating priorities is included in Annex Six.

41. In summary:

Price	9(2)(ba)(i), 9(2)(ba)(ii) [redacted]
Delivery, supply and logistics	
Additional courses and resale	
Logistical support	
Commercial considerations	

	9(2)(ba)(i), 9(2)(ba)(ii)

Janssen is seeking an indemnity from the Crown

42. Janssen is seeking a broad indemnity for liability associated with the handling, use or administration of the vaccine candidate in New Zealand. We expect this is because:

    - It is developing it in accelerated clinical trials that are less likely than non-accelerated trials to detect uncommon adverse effects or possible contraindications. COVID-19 vaccine trials are expected to be shorter and have fewer trial subjects than ordinary pharmaceutical development which will reduce the known safety profile of the vaccine.
    - It perceives risks of claims associated with the handling, use or administration of the vaccine in New Zealand.

43. 9(2)(ba)(i), 9(2)(ba)(ii)

44. 9(2)(ba)(i), 9(2)(ba)(ii)

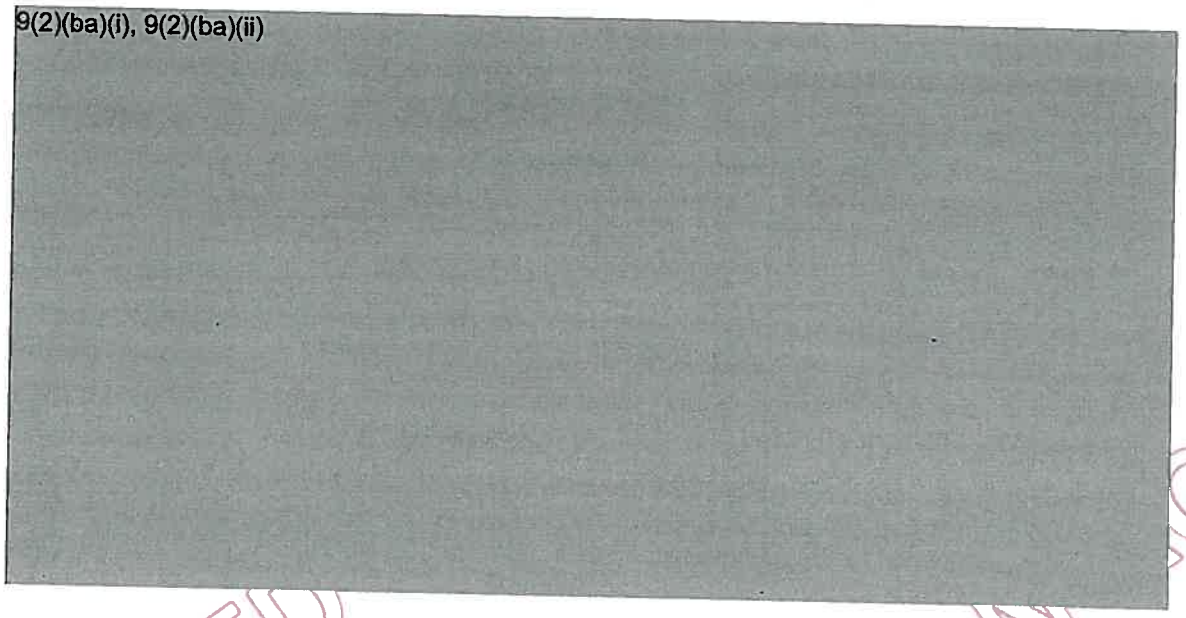
45. We will provide a business case to the Treasury on the indemnity provision negotiated as part of the APA. The Minister of Finance can give an indemnity under section 65ZD of the Public Finance Act 1989 (PFA) if it appears to the Minister to be necessary or expedient in the public interest to do so. On the basis of the business case, the Treasury will advise the Minister of Finance on whether the indemnity meets the test in the PFA.

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

46. If you agree to purchase Janssen's vaccine candidate, a draw-down from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' will be required to fund the purchase price for five million vaccines and headroom to address foreign exchange risks. A draw-down is recommended at this stage because, while the final payments for the purchase will be contingent on the successful development of the vaccine, the execution of the term sheet demonstrates a clear intention by the Government to conclude an agreement and make the purchase under the provisions in the term sheet.

47. The draw-down would enable the following payments to be made:

9(2)(ba)(i), 9(2)(ba)(ii)



Process for concluding the agreement

48. Subject to your agreement to the recommendations in this briefing, the Director-General of Health, on behalf of the New Zealand Government, will sign the term sheet attached at Annex One of this briefing.

49. Upon the execution of the term sheet we will negotiate the binding APA and your approval will be sought for the agreement of provisions in the APA.

50. If you decide to conclude the APA, your agreement will be sought separately to exercise the option to purchase three million courses of the candidate for delivery in 2022.

Other negotiations are still underway, but on a slower track

51. As well as the negotiations with the four highest priority candidates we are also in discussion with suppliers of four other vaccine candidates. Considerations about portfolio optimisation mean that these are on a slower negotiation timeline and we will not be recommending purchase decisions for them this year.

Regulatory approvals will be a separate process

52. No COVID-19 vaccine can be used as part of an immunisation strategy within New Zealand until it has received regulatory approval from Medsafe. Medsafe advises that Janssen has provided pre-submission information but it is not clear when the supplier expects to make an application.

53. Medsafe is actively considering options for expediting the approvals process in order to evaluate a number of concurrent COVID-19 applications, while ensuring that vaccines meet acceptable standards for efficacy, safety and quality.

54. This candidate is likely to be a genetically modified organism and may therefore be subject to the Hazardous Substances and New Organisms Act 1996. We understand the supplier is aware of their need to engage with the Environmental Protection Authority.

Communications and publicity

55. There is strong public interest in the efforts of pharmaceutical companies to develop effective and timely COVID-19 vaccines, and also in which countries would likely have access to vaccines once they have been developed and approved for use.

56. The conclusion of a non-binding agreement reflects the global approach taken by Janssen and other countries have made public announcements at this stage of negotiations. Subject to your agreement to execute the term sheet, we will work with Janssen, and with Ministers' offices to discuss communications and publicity opportunities.

Next steps

57. Subject to your agreement to the term sheet with Janssen, the Director-General of Health will execute the binding term sheet on behalf of New Zealand.

58. Following the execution of the term sheet we will negotiate the APA with Janssen and seek your agreement to those terms. At the same time we will provide a business case to the Treasury on an indemnity for Janssen. Your agreement to the APA will be subject to the Minister of Finance's agreement to the indemnity.

59. We will report to you over the next few weeks on the outcomes of negotiations for other APAs as they reach completion and the overall balance and assessment of the portfolio of COVID-19 vaccines.

Annexes

Annex One: Proposed Janssen Term Sheet.

Annex Two: Priority vaccine candidates and contracted delivery schedules.

Annex Three: Summary of vaccine purchase framework.

Annex Four: Summary of vaccine purchase framework analysis.

Annex Five: Science review panel commentary.

Annex Six: Summary of comparison of terms to negotiation priorities.

Annex One: Proposed Janssen Term Sheet

Annex Two: Priority vaccine candidates and contracted delivery schedules

Annex Three: Vaccine purchase decision making framework

Ideal set of information for decision making:

1. Vaccine performance	Importance
• Safety profile	CRITICAL
• Effectiveness	CRITICAL
• Ease of distribution across population as a whole or for particular population/ age groups especially Māori	HIGH
• Immunity type: sterilising vs immunity from disease	MED
2. Availability and access	
• Production ○ Confidence in company (e.g. historic performance) ○ Reliability of supply chains for raw materials ○ Capacity (incl. domestic manufacturing and flexibility) ○ Licensing arrangements ○ Delivery schedules	CRITICAL
• Price	HIGH
• Contracting ○ Type of purchasing agreement (e.g. future buy options) ○ Type of partnership incl. with other countries ○ Options to manufacture	HIGH
• 6(a) [redacted]	
• COVAX commitments	

What we can assess in absence of full information from clinical trials:

1. Vaccine performance	Importance
• Available data on safety and effectiveness (likely to be limited to preliminary or final results from Phases I/II) [Note: We are highly unlikely to enter into an APA with no indication of safety and effectiveness]	VERY HIGH
• Safety and effectiveness projections of international experts	VERY HIGH
• Existing APAs by like-minded countries	VERY HIGH
• Track record and reputation of the vaccine developer and key scientists (including signals from regulators and CEPI)	HIGH
2. Availability and access	
• Route to manufacture (arrangements in place; funding; CEPI support)	VERY HIGH

- **Track record, reputation and reliability of manufacturer** **VERY HIGH**
- **Existing APAs by like-minded countries** **VERY HIGH**
- **International risk assessment** **HIGH**
- **Price offered to other countries** **VERY HIGH**

3. Contribution to portfolio balance and strategic approach

To manage risks, the portfolio needs diversity across technology platforms, suppliers, timeframes, and equitable population coverage (including the Pacific). This will become more important over time as the portfolio builds.

Annex Four: Summary of vaccine purchase framework analysis

Annex Five: Science Review Panel Commentary

Janssen COVID-19 candidate vaccine

18th October 2020

Janssen presented its candidate viral vector vaccine to the Science Review Panel on 17th Sept 2020. There are currently no licenced vaccines using this non-replicating viral vector (the AdVac human adenovirus-based vector) technology, so it is an untested platform. Human trials for this COVID candidate vaccine are at an early stage with only early results available. Interim data from a Phase 1/2a trial show a relatively high proportion of participants experienced solicited systemic adverse events graded as severe, and although the vaccine was immunogenic, virus neutralising antibodies did not reach the same levels in some vaccines as in convalescent sera. Additionally, a phase 3 trial has been paused (13th October 2020) to investigate an SAE that occurred in a participant. It will be essential to see more data from human trials of this candidate before drawing conclusions about its safety, immunogenicity and efficacy. Animal studies for this candidate are promising, with the type of immune response (Th1, rather than Th2) not raising safety concerns. Challenge studies (where vaccinated hamsters and rhesus monkeys were dosed with the virus) showed both reduced lung disease and a potential reduction in infectiousness (via reduced viral replication in the upper respiratory tract). Approximately 67,000 people (including the elderly, HIV+, pregnant, and children over 4 months) have been vaccinated in studies of previous AdVac vaccines with no safety issues detected.

Phase 3 (efficacy) trials began in October 2020. Phase 2 and 3 studies will take place in the USA, Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa, Germany, the Netherlands, Spain and Belgium. The phase 3 trials will include adults/elderly (at least 25% of phase 3 participants over 65 years), and people with stable co-morbidities that are risk factors for severe COVID-19 disease. Pregnant women will be excluded from these studies.

This vaccine is being tested as both a 1- and 2-dose vaccine, with the 1-dose schedule being suggested by the developer as an outbreak response, and the 2-dose as potentially offering longer term protection. The vaccine will be presented in multidose vials (number of doses per vial unclear) and would be distributed in New Zealand at 2-8°C (arriving in New Zealand frozen at -20°C and can be stored frozen until distributed), which is in line with the New Zealand standard cold chain for vaccine distribution. It was mentioned that the delivery of this platform may be challenging in Pacific states. The developer will aim for 9-12 month shelf life at 2-8°C as for their other AdVac vaccines, but testing is still ongoing. It is not clear how rapidly a vial must be used after opening. As is likely to be the case for many candidate vaccines, current testing includes only those older than 18 years old and initial licensure is unlikely to include children. Data from a small number of rhesus monkeys suggest a potential effect on infectiousness (not just disease). If demonstrated in humans, this could offer a wider choice of vaccination strategies than for several other vaccines. However, substantially more data are needed before it is known if an effect on infectiousness will occur.

Janssen has a global commitment to produce 1 billion doses by the end of 2021. Manufacturing expected to commence end of 2020 in the USA, and in Italy in Q1 2021. It appears that vaccine doses can be produced rapidly, as the cell line used in production has high yields and the process is fully industrialised. There are no current plans to manufacture vaccine in the Asia-Pacific region (although opportunities in the region have been investigated).

Annex Six: Summary of comparison of terms to negotiation priorities

Application of vaccine purchase decision making framework to the Janssen Term Sheet and comment from independent experts

Purpose

This document captures information from negotiations, publicly available sources, advice from experts, and confidential information from trusted sources to apply the vaccine purchase framework to the draft binding terms being negotiated with Janssen Pharmaceutica NV ("Janssen"). Meeting the criteria in the framework informs the decision to enter an agreement with the supplier to purchase their vaccine candidate. As well as being one of the priority vaccine candidates, the framework criteria are vaccine performance, availability and access, and contribution to portfolio balance.

Process

Vaccine candidates have been prioritised and Janssen's vaccine candidate is ranked within the top four prospects for an APA (Advance Purchase Agreement). It has been judged as a suitable contributor in the construction of a portfolio of vaccine candidates for New Zealand. Negotiations to agree Heads of Terms have concluded.

Overall assessment

We believe the criteria in the purchase framework have been met:

- Performance: This is one of the two most purchased vaccine candidates in the target group. The vaccine technology has been used before in emergency situations. The early pre-clinical data on efficacy shows some promise. Many human trial participants experienced temporary side-effects. It will be essential to see full phase III data before conclusions can be drawn about safety and efficacy. Distribution requirements seem to be within the norm expected for COVID-19 vaccine candidates.
- Availability and access: There is confidence in the company and its ability to fulfil delivery commitments. Janssen, along with its parent company Johnson & Johnson, have a very strong track record in producing safe and efficacious pharmaceutical products for use globally and in New Zealand. The negotiated terms are in line with global trends for COVID-19 vaccine advance purchase arrangements. The price is settled and is represented as a global non-profit pandemic price. Assessment of international risk assessment is low-medium. The development is CEPI funded and the supplier is in negotiation with the COVAX Facility.
- Contribution to portfolio balance and strategic approach: Subject to successful clinical trials, its single-dose format offers a potentially simpler deployment model than other vaccines under consideration. The coverage in trials is broad and includes different population cohorts, so it may be able to be delivered widely across the New Zealand population, including hard-to-reach and at-risk population groups such as the elderly and those with chronic medical conditions. Quantities purchased under the agreement will be sufficient to provide broad population cover. The candidate will increase the technology diversity of the portfolio, which does not yet contain a viral vector vaccine. We are also well-advanced in negotiations with another supplier to purchase a vaccine based on similar technology.

Key to achievement of framework criteria:

- ✓✓✓ Criteria achieved with confidence, based on current information
- ✓✓ Based on the available information, nothing to indicate that criteria will not be met
- ✓ Criteria could be achieved, but there are issues to be resolved
- × Criteria is not achieved, or will not be achieved
- ◆ No indicators available at the time decisions are made

Supplier - Janssen Pharmaceutica NV "Janssen"			Vaccine Candidate: Ad26.COV2.S
Platform and description			Non-replicating viral vector vaccine[1]. Relatively new technology[2]
	Importance	Meet framework criteria	
Priority candidate groups; A, B, C	Should be in Group A	Group A	***The candidate is ranked highly in Group A*** Janssen is a highly reputable pharmaceutical firm globally. Headquartered in Beerse, Belgium, and its parent is Johnson & Johnson. Johnson & Johnson / Janssen have been in New Zealand for 85 years and have a strong presence. The supplier has a strong track record in vaccine development. They acquired vaccine production capabilities in 2011 and since then have been involved in innovative vaccine development. No Johnson & Johnson / Janssen vaccines have been used in New Zealand. However, the firm is well placed to acquire the resources needed to develop and deliver a vaccine in New Zealand[3]

[1] A non-replicating adenovirus 26 based vector expressing the stabilized pre-fusion spike (S) protein of SARS-CoV-2. Non-replicating viral vaccines work by delivering DNA into human cells that then produce vaccine antigen. The antigen stimulates s an immune response to the virus.
[2] The AdVac vector has been used in emergency situations; 67,000 people have been vaccinated with it for other diseases (e.g. RSV, HIV, Ebola, Malaria, Filo, Zika, HPV).
[3] Johnson & Johnson headquartered in New Jersey, USA has an annual turnover in excess of US$100 billion.

			The supplier has well established manufacturing capability, and is adding to that capacity. They have a partnership with the US Biomedical Advanced Research and Development Authority (BARDA), which has provided $1 billion of support for this vaccine – which demonstrates US confidence in this supplier.
Confidence in priority ranking • This is a multistep process (portfolio selection, science evaluation, international practice and independent validation).	High	✓✓✓	***There is high confidence in the ranking and the candidates sits within the top three (along with Pfizer and candidate D).*** The developer and its parent company have the resources and experience to deliver quality pharmaceutical products. The candidate is likely to be within the first group that is available for regulatory review in New Zealand, and shows some promise in early trials. Support through CEPI and a large number of APAs concluded with developed countries who have access to greater resources to vet vaccine candidates.
Vaccine performance			*What we can assess in absence of full information from trials*
Safety profile: • Aggregate and non-aggregate (taking into account population groups) • Side effects and adverse reactions	Critical	✓✓✓	**Other countries' APAs with Janssen** • US 100 million courses, UK 30 million courses, EU 400 million courses, Canada 38 million courses. Along with Candidate D, this is the most purchased vaccine candidate for APAs[4]. Comparator countries have used similar frameworks to ours, using their experts to interrogate the early science results, trial designs and manufacturing programs. The 'top list' of countries for similar safety requirements are: • Australia, Europe (centralised process), MHRA (UK), FDA (US), Canada, SwissMedic. Singapore is also comparable in terms of benefit risk assessment. **Phase I and IIa trials have been conducted or are being conducted and Phase III trials are underway** Ref NCT04436276

[4] Best of our knowledge, from publicly available sources.

			Phase I/IIa trials Safety and immunogenicity of the Ad26.COV2.S COVID-19 vaccine candidate: interim results of a phase I/IIa, double-blind, randomized, placebo-controlled trial have been published[5]. • Vaccine induced high levels of antibody responses in roughly 95% of study participants. • Healthy participants in Belgium and the U.S. between the ages of 18 and 55, as well as those 65+ participated in the trial. • Company claims to have identified clinical study sites in cities that have underserved and underrepresented populations and partnered with organizations to proactively identify and include diverse patient populations. Plans are also underway for a Phase I study in Japan, as well as a Phase II study in the Netherlands, Spain and Germany. The Phase III study commenced in September and is a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety and efficacy of a single vaccine dose versus placebo in up to 60,000 adults 18 years old and older, including significant representation from those that are over 60 years of age. The trial will include those both with and without comorbidities associated with an increased risk for progression to severe COVID-19, and will aim to enrol participants in Argentina, Brazil, Chile, Colombia, Mexico, Peru, South Africa and the United States. If successful, this design will provide a broad information base for deployment decisions. Like other major vaccine candidates, the clinical trials are not aligned with WHO Solidarity Trial. 9(2)(ba)(i), 9(2)(ba)(ii)

[5] https://www.medrxiv.org/content/10.1101/2020.09.23.20199604v1

			Science overview[6] Advantages: Previous vaccines based on this platform show low to no risk of disease enhancement. They have also been well tolerated over a large demographic range (elderly, HIV+, pregnant, children over 4 months). Risks: Human trials are still in early stages, so few safety data are available. It will be essential to see full phase I/II data before reaching any conclusions about safety, but interim analyses after dose 1 show a relatively high proportion of 18-55 year old participants experienced side-effects. Fewer participants over 65 years experienced adverse events. As with other COVID-19 candidate vaccines, there is the potential for safety issues including disease enhancement after vaccination. In pre-clinical studies, a dominant T helper 1 response was seen, reducing the theoretical risk of vaccine-associated enhanced disease, but results in humans are not yet available.
Effectiveness • Aggregate and non-aggregate	Critical	✓ ✓ ✓	**Other countries' APAs with Janssen** *See discussion above* **Science overview**[7] Advantages: *Immunogenicity*: The attributes of previous vaccines based on this platform match the WHO key immunogenicity attributes for platforms to be prioritised for COVID-19 vaccine. These include: 1 dose regimen, production of neutralising antibody, Cell Mediated Immunity response and duration of immunity. *Efficacy* The animal data for this vaccine are impressive (e.g. some suggestion that might reduce infectiousness, not just disease severity), but clinical data are necessary to determine if that translates to efficacy in humans. The developer appears to be using sensible approaches, but we are missing some information to be certain.

[6] The framework incorporates comments from the Science Review Panel's Commentary and Overview, both dated 18 October 2020.
[7] The framework incorporates comments from the Science Review Panel's Commentary and Overview, both dated 18 October 2020.

			Risks: *Immunogenicity* Human trials are still in early stages, so only interim (post-dose 1) human immunogenicity are available. These interim data show virus-neutralising antibody in vaccines to be at a somewhat lower concentration than in convalescent sera[8]. The immune response might also be lower in those over 65 years than in those aged 18-55 years, but data are very scarce to date. It will be essential to see full immunogenicity data before reaching any conclusions about immunogenicity[9]. The vector is human adenovirus based, so there is a theoretical potential that patients with prior exposure to adenovirus may have an immune response to the vector. Although pre-existing antibody did not interfere with immunogenicity in Ad26-seropositive rhesus monkeys, no human data are yet available to address this issue (phase I/IIa data to date talks only of pre-existing antibody to SARS-CoV-2, not Ad26). *Efficacy* No human efficacy data are available for this vaccine. It will be essential to see phase III data before reaching any conclusions about efficacy. The AdVac platform is also used in a licensed Ebola vaccine, but there are no clinical efficacy data available (presumably due to insufficient Ebola cases to conduct a trial). *Suitability for specific population groups* Trials are being conducted in a wide range of demographic groups, including the elderly and those with chronic medical conditions. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]
Ease of distribution:	High	✓✓✓	***Single dose vaccine would have significant advantages, other administrative requirements*** *Administration of vaccine*

[8] Blood serum obtained from an individual who has recovered from an infectious disease and contains antibodies against the infectious agent of the disease.

[9] When human immunogenicity data become available it will not be clear if assays will be comparable to those used by other vaccine developers, and whether it will be possible to compare immunogenicity across vaccines (this issue is common to all candidate vaccines).

			The total dosage and administration schedule required to immunize an individual will be confirmed in clinical trials. Janssen currently represents the regimen, for addressing the acute stage of the pandemic, as a single $1x10^{11}$ viral particles (/.5ml) dose vaccine injection. Clinical trials will still evaluate a regimen of two injections of $5x10^{10}$ viral particles (/.25 ml) given with a 2-month interval in between. A single dose may be sufficient in an outbreak setting (by reducing transmission rates), although two doses could potential provide longer term protection (by maintaining levels of immunity). Data from clinical trials of 1 vs. 2 doses will be important for determining this, and developers will continue to assess any need for booster doses (e.g. annual booster). It does not use a preservative, this increases the acceptability of the vaccine. There are significant administrative advantages if the vaccine can be successfully delivered in a single dose regimen – increased effectiveness (no need to recall recipients and no issues of recipients failing to present for the second dose), and less costly to administer. A single dose and broad range of cover may make this candidate more suitable than others for delivery to hard to reach populations, including in the Pacific. *Presentation and storage* • The vaccine will be delivered in multi-dose vials without preservative. • All doses of a vial may need to be used within 6 hours of first administration of a dose from the vial. • This vaccine would be distributed in New Zealand at 2-8°Celcius .The 2-8°Celcius distribution is in line with the New Zealand standard cold chain process for vaccine distribution. • The pproduct will be delivered to one location of the government's direction at 2-8 degrees. The shelf life of three months will have started from the time it was thawed for shipment from the central distribution hub.

			• Shelf life testing at 2-8°Celcius is underway, and will likely extend as more data become available.[10]
Availability and access			
Production: • Confidence in developer • Reliability of supply chains for raw materials • Capacity (including domestic manufacturing and flexibility) • Delivery schedules • Technology platform • Licensing arrangements	Critical	✓✓✓	***There is confident in the supplier's ability as a developer.*** Janssen, as part of Johnson & Johnson, have the resources needed to develop the product. They acquired vaccine production capabilities in 2011 and since then have been involved in innovative vaccine development.[11] ***There is confidence in Janssen's capacity and capability to manufacture quality products in the quantities needed.*** Janssen, as part of Johnson & Johnson, have a proven record of manufacturing at scale. • Is establishing its own, as well as external, manufacturing capacities around the world in order to meet the expected global demand. • The investigational vaccines were produced at Janssen's facility in Leiden, the Netherlands. • 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

[10] The developer will aim for 9-12 months as for their other AdVac vaccines. By January 2021 they expect a 3-6 month shelf life at 2-8°C to be confirmed.

[11] Ebola vaccine, which has been used in the Democratic Republic of the Congo (DRC) and Rwanda, Zika, RSV and HIV vaccine candidates.

			Vaccine acceptability May be relevant for sensitive groups because: • The source of the cell line used to manufacture the vaccine is a cell line isolated from a human foetus in the 1980s. • The vaccine is technically a genetically modified organism, and discussion/engagement with the public in New Zealand may be needed. ***Distribution plan and delivery schedule are agreed and satisfactory*** The finished product will be delivered directly from Janssen's central distribution hub (location TBD) to one location of the government's direction, and will not go through local J&J warehouses or facilities. Janssen has a global commitment to produce 1 billion doses by the end of 2021. Delivery schedule 9(2)(ba)(i), 9(2)(ba)(ii) 9(2)(ba)(i), 9(2)(ba)(ii) ***Technology platform*** The attributes of previous vaccines based on this platform match the WHO key attributes for platforms to be prioritised for COVID-19 vaccines[12].

[12] These include: 1 dose regimen, production of neutralising antibody, CMI response, low to no risk of disease enhancement, development speed, capability to scale up (PER.C6 has high yields and is fully industrialised), duration of immunity, and vaccine stability (2 years for HIV and 9 months for Ebola at 2-8°C).

			There are no options for manufacturing in New Zealand during the pandemic period There are no current plans to manufacture vaccine in the Asia-Pacific region for the pandemic period (although opportunities in the region were investigated). ***Regulatory issues*** • 9(2)(ba)(i), 9(2)(ba)(ii) • This is technically a genetically modified organism. The supplier has been informed of the need to engage with the Environmental Protection Authority. • Have commenced pre-submission meetings with Medsafe, but there are no indications of when the supplier will be in a positon to apply for approval.
Contracting: • Type of purchasing agreement • Partnership with other countries • Options to manufacture • COVAX implications	High	✓✓✓	Parties are negotiating a Heads of Terms sheet[13], that sets out the terms and conditions which are expected to be carried over to the APA[14]. We understand this is the global approach taken by Janssen. • 9(2)(ba)(i), 9(2)(ba)(ii) The indemnity provisions in the agreement are the subject of a business case, which will be provided separately to the Treasury. Supplier is in negotiations with COVAX Facility, so Janssen vaccines may also become available through the Facility.
International risk assessment: • Health, economic and social impacts of	High	Low to medium	There is some distributional risk and otherwise low reputational and geopolitical risk, and moderate supply chain risk associated with purchase of this candidate. These international risk considerations should not preclude purchase of this candidate, subject to ongoing

[13] A non-binding expression of interest.

[14] Neither party is obligated to enter into the APA, negotiations may be abandoned by any party prior to entering an APA. New Zealand has signalled the desire to negotiate the APA within four weeks of the execution of the heads of terms agreement.

pandemic (impacts on demand and availability) • State support for development and manufacturing • Sovereign hoarding • US election • COVAX commitments			monitoring to ensure adequate measures are in place to mitigate supply chain and distributional risks[15]. Have received support for development from: • CEPI. • Bill & Melinda Gates Foundation • US Department of Defence, and US Department of Health and Human Services Biomedical Advanced Research and Development Authority CEPI funded so (if successfully developed) likely to be offered through COVAX Facility. *Would we want more if offered through the COVAX Facility?* Possibly yes, if offered earlier than 2022 deliveries.
Number of courses		✓✓✓	5 million[16] made up of: • 9(2)(ba)(i), 9(2)(ba)(ii) 9(2)(ba)(i), 9(2)(ba)(ii)
Cost per coarse		✓✓✓	9(2)(ba)(i), 9(2)(ba)(ii)

[15] MFaT risk assessment dated 20 November 2020.
[16] Original offer was for 4 million.
[17] Janssen's intention is to offer a single global price based on Janssen's global not-for-profit framework.

			9(2)(ba)(i), 9(2)(ba)(ii)
Contribution to portfolio balance			
Diversity of vaccine platforms (proxy for immunological response)		✓✓✓	New platform to portfolio, but potential overlap in technology platform with candidate D. The US, EU and UK also have this overlap. The portfolio approach allows for such overlaps – to mitigate risks of vaccine development failure and unsuitability of the vaccine for delivery.
Diversity of suppliers		✓✓✓	New supplier. Manufacturing is likely to be in India, so different from other target candidates.
Equitable population coverage (including the Pacific)		✓✓✓	Sufficient for population-wide coverage, including for Polynesia.
Early access/Delivery timeframes		✓✓✓	9(2)(ba)(i), 9(2)(ba)(ii) So, likely to be delivered within the same time range as most other group A candidates.

Other matters not part of the framework analysis		
Suitability for different population groups	◆	Unlikely to be able to determine this at the time decisions are made, but cover is expected to be broad.
Duration of immunity	◆	Unlikely to be able to determine this at the time decisions are made.
Immunity type	◆	Unlikely to be able to determine this at the time decisions are made.
Multi-lateral or bilateral		Bilateral
APAs concluded by New Zealand		No other APAs have been concluded, but New Zealand is committed to conclude an APA to purchase 750,000 courses of Pfizer's vaccine candidate.

13 November 2022

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

MINISTRY OF HEALTH
MANATŪ HAUORA

BRIEFING

Supply agreement for purchase of COVID-19 vaccines from Janssen Pharmaceutica NV

Date:	18 December 2020	**Priority:**	Urgent
Security classification:	Sensitive	**Tracking number:**	2021-1849

Action sought

	Action sought	Deadline
Rt Hon Jacinda Ardern **Prime Minister** Hon Grant Robertson **Minister of Finance** Hon Dr Megan Woods **Minister of Research, Science and Innovation** Hon Chris Hipkins **Minister for COVID-19 Response** Hon Andrew Little **Minister of Health**	**Agree** that the Director-General of Health execute a definitive supply agreement with Janssen Pharmaceutica NV for the purchase of two million doses of COVID-19 vaccines (with an option to purchase three million more).	21 December 2020
Hon Dr Ayesha Verrall **Associate Minister of Health**	**Note** contents of the paper.	None

Contact for telephone discussion (if required)

Name	Position	Telephone	1st contact
Poppy Haynes	Manager, COVID-19 Vaccine Purchase, MBIE	9(2)(a)	✓
Maree Roberts	Deputy Director-General, System Strategy & Policy, MoH	9(2)(a)	
Bhagee Ramanathan	Principal Policy Advisor, MBIE	9(2)(a)	

The following departments/agencies have been consulted

PHARMAC, MBIE, MoH, MFAT, The Treasury, DPMC, Medsafe

Minister's office to complete:

- ☐ Approved
- ☐ Noted
- ☐ Seen
- ☐ See Minister's Notes
- ☐ Declined
- ☐ Needs change
- ☐ Overtaken by Events
- ☐ Withdrawn

Comments

MINISTRY OF HEALTH
MANATŪ HAUORA

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Supply agreement for purchase of COVID-19 vaccines from Janssen Pharmaceutica NV

Date:	18 December 2020	**Priority:**	Urgent
Security classification:	Sensitive	**Tracking number:**	2021-1849

Purpose

To seek approval for the Director-General of Health to execute a definitive supply agreement for the already announced purchase of two million courses (with an option to purchase three million more) of a potential vaccine against COVID-19 from Janssen Pharmaceutica NV.

Executive summary

Background

In November, Ministers agreed to a non-binding heads of terms agreement with Janssen Pharmaceutica NV (Janssen) for a purchase of two million courses of a viral vector vaccine, with an option to purchase an additional three million, for delivery in 2021 and 2022 (briefing *MBIE 2021-1195* refers). Ministers had previously agreed in early October to a binding heads of terms agreement to an offer from Pfizer Inc. (Pfizer) for the purchase of 750,000 courses of an mRNA vaccine candidate for delivery early 2021 (briefing MBIE 2021-0996 refers). Both of these arrangements require a definitive supply agreement to be negotiated and executed. We are providing advice to you about the conclusion of a definitive supply agreement with Pfizer in parallel with this briefing (briefing MBIE 2021-1847 refers).

Earlier this month, Joint Ministers agreed to binding supply agreements with AstraZeneca Ltd. for the delivery of 3.8 million courses of a viral vector vaccine (briefing MBIE 2021-1537 refers) and with Novavax Inc. for the purchase of 5.36 million courses of a protein sub-unit vaccine (briefing MBIE 2021-1723 refers), both for delivery as early as the second quarter of 2021.

New Zealand announced the purchase from Janssen on 19 November. The purchase was negotiated as a non-binding heads of terms agreement to be followed by a binding definitive supply agreement that would be more detailed and include other supply matters.

We recommend that you agree to conclude a definitive supply agreement with Janssen to secure the purchase of their vaccine candidate

In a market where supply is constrained, a definitive supply agreement should be executed without delay to secure access to the available Janssen vaccines. This need is particularly pressing because the heads of terms agreed with Janssen is not legally binding and because the vaccine portfolio currently only includes one other candidate that can provide at least five million courses.

The proposed definitive supply agreement has been negotiated with the advice of legal and commercial experts. An interagency approach (including PHARMAC) was taken in the negotiations and an appropriate outcome has been achieved. We seek your agreement to execute the proposed definitive supply agreement (attached at Annex One).

The proposed supply agreement's substantive terms were agreed in the non-binding heads of terms agreement with Janssen. A number of general supply terms commonly found in agreements for the purchase of medicines are included in the supply agreement such as product specifications

and processes to be used to order and take delivery of the vaccines. Annex Two outlines noteworthy additional or amended terms for the proposed purchase agreement, the main ones are:

- 9(2)(ba)(i), 9(2)(ba)(ii)
- 9(2)(ba)(i), 9(2)(ba)(ii)
- 9(2)(ba)(i), 9(2)(ba)(ii)
- 9(2)(ba)(i), 9(2)(ba)(ii)

We do not consider that the increased risk from the unfavourable changes precludes concluding the proposed definitive supply agreement. 9(2)(ba)(i), 9(2)(ba)(ii) is favourable to New Zealand as clinical trial results (due in January 2021) can be factored into that decision.

As previously advised, Janssen have sought an indemnity from the Crown (briefing MBIE 2021-1195 refers). The Minister of Finance is required to approve the indemnity provisions in the definitive supply agreement and to sign the supply agreement as a counterparty in respect of those indemnity provisions. Treasury officials will advise the Minister of Finance on the indemnity provisions in the proposed definitive supply agreement.

Since executing the non-binding heads of terms agreement, no new clinical results have become available about the candidate nor any other information that would indicate that a definitive supply agreement should not be concluded.

Next steps

Subject to your agreement to the recommendations in this briefing and the agreement of the Minister of Finance to grant Janssen an indemnity, the Director-General of Health, on behalf of the New Zealand Government, will sign the proposed definitive supply agreement (attached at Annex One). The Minister of Finance will be required to approve the indemnity provisions in the definitive supply agreement and to sign the supply agreement as a counter party in respect of those provisions.

9(2)(ba)(i), 9(2)(ba)(ii)

Given that the arrangement with Janssen was announced last month as an intention to purchase, there may be public interest in the conclusion of the arrangement. After discussion with your offices, we will work with Janssen to consider whether a further announcement about the execution of the definitive supply agreement should be made.

Recommended action

The Ministry of Business, Innovation and Employment, and the Ministry of Health recommend that you:

a) **Note** the information in this briefing is subject to confidential disclosure agreements with vaccine developers and should be treated as commercially sensitive.

Noted

b) **Note** an unprecedented global health crisis continues and the New Zealand population remains almost totally susceptible to COVID-19 due to our successful elimination strategy.

Noted

c) **Note** the global demand for COVID-19 vaccines continues to be high and capacity to manufacture successful vaccine candidates is heavily constrained worldwide, and this situation is likely to continue for some time. Advanced economies are pre-purchasing multiple COVID-19 vaccine candidates to mitigate the risk of development failure.

Noted

d) **Note** in early October, Ministers agreed to the terms of a binding heads of terms arrangement with Pfizer Inc. for the purchase of 750,000 courses of an mRNA vaccine candidate for delivery early next year (briefing MBIE 2021-0996 refers). You have received advice about the conclusion of a definitive supply agreement with Pfizer (briefing MBIE 2021-1847 refers).

Noted

e) **Note** earlier this month, Ministers agreed to a binding supply agreement with AstraZeneca Ltd for the purchase of 3.8 million courses of a viral vector vaccine (briefing MBIE 2021-1537 refers), and with Novavax Inc. for the purchase of 5.36 million courses of a protein sub-unit vaccine (briefing MBIE 2021-1723 refers), both for delivery as early as the second quarter of 2021.

Noted

f) **Note** in mid-November, Ministers agreed to the terms of a non-binding heads of terms arrangement with Janssen for the purchase of two million courses of a viral vector vaccine, with an option to purchase three million more courses, for delivery in 2021 and 2022 (briefing MBIE 2021-1195 refers). The agreement was announced on 19 November and requires parties to conclude a definitive supply agreement.

Noted

g) **Note** the execution of a definitive supply agreement without delay is important to secure the purchase of Janssen's vaccine candidate.

Noted

h) **Note** a definitive supply agreement has been negotiated with Janssen (attached as Annex One). An inter-agency approach (including PHARMAC), has continued for these negotiations. Advice was taken from legal and commercial experts and officials consider that appropriate terms have been negotiated.

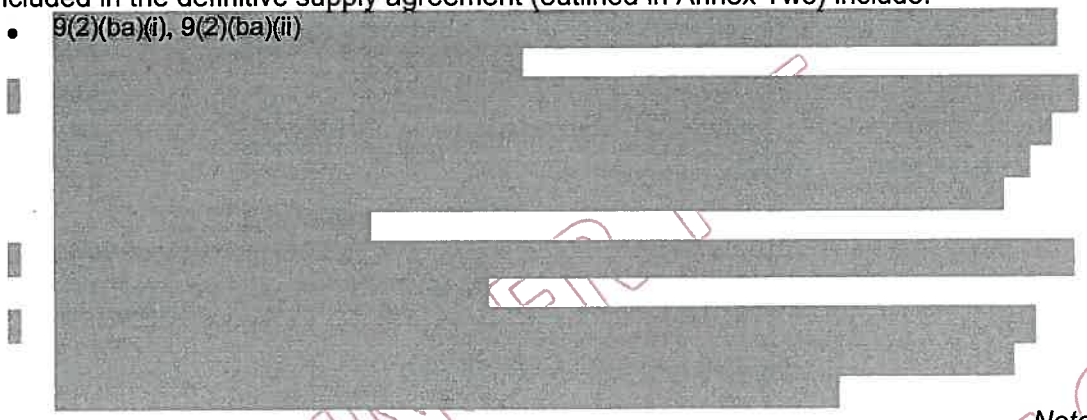
Noted

i) **Note** the substantive terms of the proposed supply agreement negotiated with Janssen were agreed in the non-binding heads of terms arrangement executed in November. The proposed agreement also includes a number of general supply terms, not inconsistent with the non-binding arrangement and commonly found in agreements for the purchase of medicines, such as product specifications and processes to be used to order and take delivery of the vaccines.

Noted

j) **Note** new or amended significant terms, from those in the heads of terms agreement, included in the definitive supply agreement (outlined in Annex Two) include:

- 9(2)(ba)(i), 9(2)(ba)(ii)



Noted

k) **Agree** that that the Director-General of Health execute the proposed definitive supply agreement for the purchase of two million courses, with an option to purchase three million more, of Janssen's vaccine on behalf of the New Zealand Government (the terms of the proposed supply agreement are attached in Annex One). Your agreement is subject to the agreement of the Minister Finance to grant Janssen an indemnity.

Agree / Disagree

l) **Note** that the Minister of Finance is required to sign the proposed definitive supply agreement as a counterparty in respect of the indemnity provisions in the agreement. Treasury officials will advise the Minister of Finance on the indemnity required by Janssen.

Noted

m) **Note** Ministers have agreed to draw down 9(2)(ba)(i), 9(2)(ba)(ii) from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' to purchase the Janssen vaccine candidate (briefing MBIE 2021-1195 refers).

Noted

Rt Hon Jacinda Ardern

Prime Minister

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

Hon Grant Robertson

Minister of Finance

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

Hon Dr Megan Woods

Minister of Research, Science, Innovation

…../…../…..

Hon Chris Hipkins

Minister for COVID-19 Response

…../…../…..

Hon Andrew Little

Minister of Health

…../…../…..

Maree Roberts

Deputy Director-General,

Ministry of Health

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

Dr Peter Crabtree

General Manager, Science, Innovation and International, MBIE

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

Background

Global demand for COVID-19 vaccines remains high

1. An unprecedented health crisis continues worldwide, and New Zealand's population remains entirely susceptible to COVID-19 due to our successful elimination strategy.

2. Our ability to recover from the COVID-19 pandemic and relax public health controls relies on the availability of safe and effective COVID-19 vaccines. The global demand for COVID-19 vaccines continues to be high and capacity to manufacture successful vaccine candidates is heavily constrained worldwide. This constraint is expected to continue for some time.

Ministers have previously agreed to a COVID-19 vaccine purchasing strategy and a framework to guide purchase decisions

3. In May, Cabinet agreed a purchasing strategy to support acquisition of COVID-19 vaccines [CAB 20-MIN-0382] with the objective of managing a range of risks and providing safe and effective COVID-19 vaccines to implement the Government's preferred immunisation strategy for New Zealand and for use in the Pacific.

4. Once concluded, advance purchase agreements (APAs) will commit New Zealand to the purchase of vaccines, conditional on successful clinical trials of the vaccine candidate and regulatory approval in New Zealand. Money spent on APAs will be lost if the development is unsuccessful, if the candidate is found to be unsuitable for deployment as part of the Government's preferred immunisation strategy, or if the supply is in excess of what is required under that strategy and cannot be on-sold. In the current global context, this is the cost of attempting to secure supply of vaccines that are still being developed.

Ministers have agreed to terms to purchase four COVID-19 vaccine candidates

5. In early October this year, Ministers agreed to the terms of a binding heads of terms agreement with Pfizer Inc. (Pfizer) for the purchase of 750,000 courses of an mRNA vaccine candidate for delivery early next year (briefing MBIE 2021-0996 refers). It requires parties to conclude a definitive supply agreement and, in parallel with this briefing, you have received advice about the conclusion of the agreement with Pfizer (briefing MBIE 2021-1847 refers).

6. In mid-November, Ministers agreed to non-binding heads of terms from Janssen Pharmaceutica NV (Janssen) for the purchase of two million courses of a viral vector vaccine, with an option to purchase an additional three million courses, for delivery in 2021 and 2022 (briefing MBIE 2021-1195 refers). The non-binding agreement was announced on 19 November and requires parties to conclude a definitive supply agreement in order for the arrangement to become legally binding.

7. Earlier this month, Ministers agreed to enter into a binding supply agreement with AstraZeneca Ltd for the purchase of 3.8 million courses of a viral vector vaccine (briefing MBIE 2021-1537 refers), and with Novavax Inc. for the purchase of 5.36 million courses of a protein sub-unit vaccine (briefing MBIE 2021-1723 refers), both for delivery as early as the second quarter of 2021.

Concluding the definitive supply agreement with Janssen is critical to securing a 'corner-stone' vaccine in our portfolio

8. The heads of terms agreed for the purchase of Janssen's candidates, while demonstrating a clear intention by all parties to conclude a binding agreement, do not constitute legal obligations on Janssen to supply their vaccine candidate to New Zealand.

9. While the global supply of vaccines continues to be constrained, we consider that it is imperative to secure the available vaccines from Janssen by concluding a definitive supply agreement without delay.

10. The Janssen vaccine plays a key role in New Zealand's core vaccine portfolio: it is a promising candidate that is potentially a single-dose vaccine (see discussion below), and available in sufficient quantities to potentially provide five million courses within the timeframes required to implement the immunisation programme. A potentially single dose vaccine could be well suited for use in the Pacific.

11. The importance of securing Janssen's vaccine for our portfolio has increased 9(2)(ba)(i), 9(2)(ba)(ii) The needs of our vaccine portfolio could change as more information is known, but at this stage, the Vaccine Taskforce considers that the core portfolio has insufficient vaccine options that are available in sufficient quantities to provide five million courses, and without the Janssen purchase the portfolio would be even less resilient.

A proposed supply agreement, in line with the non-binding terms previously agreed with Janssen, has been negotiated

12. We have negotiated a proposed definitive supply agreement with Janssen (attached as Annex One), and appropriate terms for the purchase of potential COVID-19 vaccines have been achieved. An inter-agency approach, including PHARMAC, has continued for these negotiations. Legal and commercial advice from Bell Gully and others was taken during the negotiation.

13. The substantive terms of the proposed definitive supply agreement were negotiated in the binding heads of terms arrangement.

14. A number of general supply terms not inconsistent with the non-binding heads of agreement, commonly found in agreements for the purchase of medicines, such as product specifications, manufacturing and quality standards, and processes to be used to order, take delivery and administer the vaccines, are included in the proposed definitive supply agreement. Noteworthy changes to the agreement are outlined in Annex Two. They include:

- 9(2)(ba)(i), 9(2)(ba)(ii)

15. We do not consider that the risks from the unfavourable changes precludes concluding the proposed definitive supply agreement. 9(2)(ba)(i), 9(2)(ba)(ii)

9(2)(ba)(i),9(2)(ba)(ii) is favourable to New Zealand as we will be able to factor clinical trial results (due in January) into that decision.

Janssen is seeking an indemnity from the Crown

16. As previously advised, Janssen is seeking an indemnity for liability associated with the handling, use or administration of the vaccine candidate in New Zealand (briefing MBIE 2021-1195 refers).

17. We will provide a business case to the Treasury on the indemnity provision negotiated as part of the definitive supply agreement. The Minister of Finance can give an indemnity under section 65ZD of the Public Finance Act 1989 (PFA) if it appears to the Minister to be necessary or expedient in the public interest to do so. On the basis of the business case, the Treasury will advise the Minister of Finance on whether the indemnity meets the test in the PFA.

18. Your agreement that the Director-General execute the definitive supply agreement is subject to the Minister of Finance's agreement to grant an indemnity to Janssen. The Minister of Finance is required to approve the indemnity provisions in the definitive supply agreement and to sign the supply agreement as a counter party in respect of those provisions.

No new information about the candidate has become available since the non-binding heads of terms was agreed

19. Since executing the non-binding heads of terms agreement, no new clinical results about the vaccine candidate have become available, nor any other information that would indicate that a definitive supply agreement should not be concluded.

Communications and publicity

20. As the arrangement with Janssen was announced last month as an intention to purchase rather than as a confirmed purchase, there may be public interest in the conclusion of the definitive supply agreement.

Next steps

21. Subject to your agreement to the execution of the proposed definitive supply agreement and the Minister of Finance's agreement to provide an indemnity to Janssen, the Director-General of Health will sign the proposed definitive supply agreement with Janssen on behalf of New Zealand. The Minister of Finance will also sign as a counterparty in relation to the indemnity provisions in the agreement.

22. The advance payment for two million courses and the payment for the option to purchase an additional three million, 9(2)(ba)(i), 9(2)(ba)(ii)

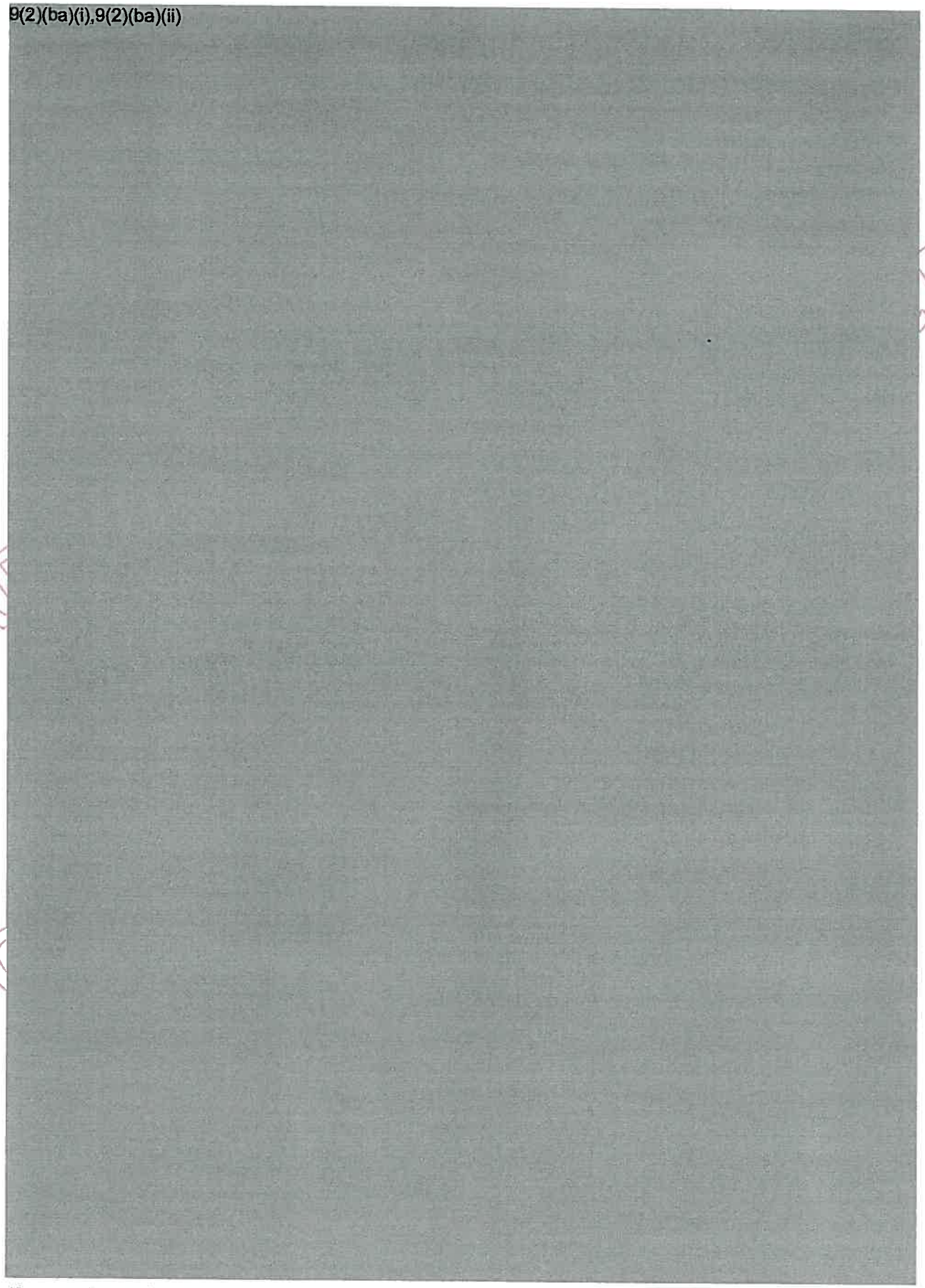
23. After discussion with your offices, we will work with Janssen, on a possible announcement about the execution of a definitive supply agreement with Janssen.

Annexes

Annex One: Proposed definitive supply agreement with Janssen.

Annex Two: Summary of notable new or amended provisions in the proposed definitive supply agreement.

9(2)(ba)(i),9(2)(ba)(ii)



MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

MINISTRY OF HEALTH
MANATŪ HAUORA

BRIEFING

Purchase of COVID-19 vaccines from Novavax Inc.

Date:	11 December 2020	**Priority:**	Urgent
Security classification:	Sensitive	**Tracking number:**	2021-1723

Action sought		
	Action sought	**Deadline**
Rt Hon Jacinda Ardern **Prime Minister** Hon Grant Robertson **Minister of Finance** Hon Dr Megan Woods **Minister of Research, Science and Innovation** Hon Chris Hipkins **Minister for COVID-19 Response** Hon Andrew Little **Minister of Health**	**Agree** to terms to purchase 5.36 million courses of a vaccine against COVID-19 from Novavax Inc.	14 December 2020 (end of day)
Hon Nanaia Mahuta **Minister of Foreign Affairs** Hon Dr Ayesha Verrall **Associate Minister of Health**	**Note** contents of the paper	None

Contact for telephone discussion (if required)			
Name	**Position**	**Telephone**	**1st contact**
Poppy Haynes	Manager, COVID-19 Vaccine Purchase, MBIE	9(2)(a)	✓
Maree Roberts	Deputy Director-General, System Strategy & Policy, MoH	9(2)(a)	
Bhagee Ramanathan	Principal Policy Advisor, MBIE	9(2)(a)	

The following departments/agencies have been consulted
PHARMAC, MBIE, MoH, MFAT, The Treasury, DPMC, Medsafe

Minister's office to complete:

- ☐ Approved
- ☐ Noted
- ☐ Seen
- ☐ See Minister's Notes
- ☐ Declined
- ☐ Needs change
- ☐ Overtaken by Events
- ☑ Withdrawn

Comments

MINISTRY OF HEALTH
MANATŪ HAUORA

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Purchase of COVID-19 vaccines from Novavax Inc.

Date:	11 December 2020	**Priority:**	Urgent
Security classification:	Sensitive	**Tracking number:**	2021-1723

Purpose

To seek approval to terms for the purchase of 5.36 million courses of a potential vaccine against COVID-19 from Novavax Inc. (Novavax). The vaccines are expected to be delivered as early as the second quarter of 2021 (subject to successful development and regulatory approval). Your agreement to the terms of the purchase agreement is subject to the Minister of Finance agreeing to provide an indemnity to Novavax and specific associated persons.

Executive summary

Background

Our ability to recover from the COVID-19 pandemic and relax public health controls relies on the availability of safe and effective COVID-19 vaccines. The global demand for COVID-19 vaccines continues to be high, and the capacity to manufacture vaccines remains heavily constrained.

In response to these challenges the Government has:

- approved the Vaccine Strategy [CAB-20-MIN-0229.01] with the objective of ensuring access to safe and effective vaccines for New Zealand and the Pacific.
- established a tagged contingency of up to $600 million [CAB-20-MIN-382] for purposes of purchasing suitable vaccines, including entering into advance purchase agreements (APAs) to purchase potential COVID-19 vaccines, and has delegated purchase decisions to the Prime Minister, the Minister of Finance, the Minister of Research, Science and Innovation and the Minister of Health (Joint Ministers).
- through Joint Ministers, agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (briefing MBIE 2021–0662 refers).
- increased the tagged contingency to $1,050 million and added the Minister for COVID-19 Response to the Joint Ministers decision-making group [CAB-20-MIN-0508].
- agreed that up to $75 million be allocated from Vote Official Development Assistance to support Pacific and global vaccine access and roll-out [CAB-20-MIN- 0504].

The 'ideal' vaccine is not yet available to buy. The purchasing strategy aims to pre-purchase a portfolio of potential vaccines through APAs at a stage where the candidates still carry a risk of failure. To assist with our decisions to enter into APAs we have early information about candidate performance, information about manufacturing processes and plans, and other countries' decisions to enter into APAs.

Money spent on APAs may be lost if the development is unsuccessful, if the candidate is found to be unsuitable for deployment as part of the Government's preferred immunisation strategy, or if the supply is in excess of what is required under that strategy and cannot be on-sold. In the current global context, this is the cost of attempting to secure supply of vaccines that are still being developed.

A purchase agreement with Novavax is a key component in a 'core portfolio' of COVID-19 vaccines

Of the vaccine candidates under development globally, the Vaccine Taskforce prioritised concluding negotiations with four suppliers by the end of the year: Pfizer Inc. (Pfizer), AstraZeneca Ltd (AstraZeneca), Janssen Pharmaceutica NV (Janssen) and Novavax New Zealand has committed to agreements with the first three suppliers.

The proposed purchase agreement with Novavax is for 5.36 million courses of its vaccine candidate, sufficient for broad coverage of New Zealand and Polynesia. At around [redacted] course (consisting of two doses), the purchase price is at the higher end of the price range for vaccines in our portfolio. We recommend drawing-down 9(2)(ba)(i), 9(2)(ba)(ii) from the "Minimising the health impacts of COVID-19 – Tagged Operating Contingency" to fund the purchase of the vaccines and to address foreign exchange risk. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] The negotiated purchase offer, which is a legally binding full purchase agreement, is attached in Annex One.

Novavax's offer is time-limited, and it is imperative that the purchase agreement is concluded promptly in order to secure the vaccines for New Zealand from a global allocation.

This purchase makes a key contribution to our 'core portfolio' and meets the purchase framework criteria

Despite 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] some delivery risk, we consider that the vaccine would play a pivotal role in our portfolio, creating optionality and including a very promising candidate. We recommend agreeing to the Novavax offer because:

- early results suggest that this vaccine provokes a strong immune response and may have the potential to prevent disease transmission, though, like the other three already purchased candidates, causes temporary side-effects.
- subject to clinical trials, it could provide broad population cover within the timeframes required to implement the immunisation programme planned for 2021 and 2022.
- it would add critical optionality to the 'core portfolio' by including a promising technology platform (so far we can only provide wide population cover with viral vector vaccines).
- it is a widely purchased vaccine globally, and our own purchase framework analysis supports those decisions.
- though there is a higher delivery risk than other purchased candidates, we are confident of the company's ability to manufacture and deliver the vaccine in the agreed timeframes.
- the terms of the proposed arrangement are reasonably favourable to New Zealand.

The proposed purchase meets the criteria in the purchase framework which considers vaccine performance, availability and access, contribution to portfolio balance, and strategic. We have taken advice from Bell Gully, and an independent science advisory panel during the negotiation. PHARMAC has also been involved.

The needs of the portfolio may change over time as more information is available. At this time we consider the 'core portfolio' needs at least four different vaccine candidates, each offering wide population coverage. This would be our third broad application purchase. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] We consider that the portfolio lacks sufficient broad coverage 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] Therefore, in addition to the purchase from Novavax, a further high-volume purchase, and one or two smaller purchases, including purchases through the COVAX Facility, may be necessary to give the portfolio sufficient diversity to provide a high degree of confidence that it will achieve the Vaccine Strategy's objectives, including full coverage for New Zealand and to support access to the vaccine in Polynesia.

All COVID-19 vaccine suppliers are requiring indemnities from purchases to protect against a range of risks. In normal circumstances many of these risks can be covered by insurance, but this is not possible in the case of COVOD-19 vaccines. 9(2)(ba)(i), 9(2)(ba)(ii) We are advised that the risks associated the Novavax indemnity seem likely to be relatively low.

Regulatory approval

Safety and effectiveness will need to be established before COVID-19 vaccines are deployed. We understand that Novavax has had preliminary discussions with Medsafe and are aware of the need to engage with the Environmental Protection Authority to determine whether this vaccine is subject to the authority's approval under the Hazardous Substances and New Organisms Act 1996.

Next steps

Subject to your agreement to the recommendations in this briefing, and the Minister of Finance's agreement to provide an indemnity for Novavax and specific associated persons, both the Director-General of Health on behalf of the New Zealand Government and the Minister of Finance, will sign the proposed supply agreement (attached at Annex One).

Subject to your agreement to the purchase terms with Novavax, and following discussions with advisers in your offices, we propose to announce this and the agreement with AstraZeneca, at a media event led by the Prime Minister in Auckland on 17 December.

We will report to you over the next few weeks on the conclusion of APAs with Pfizer and Janssen.

Recommended action

The Ministry of Business, Innovation and Employment, and the Ministry of Health recommend that you:

a) **Note** the information in this briefing is subject to confidential disclosure agreements with vaccine developers and should be treated as commercially sensitive.

Noted

b) **Note** an unprecedented global health crisis continues and the New Zealand population remains almost totally susceptible to COVID-19 due to our successful elimination strategy.

Noted

c) **Note** the global demand for COVID-19 vaccines continues to be high, and capacity to manufacture successful vaccine candidates is heavily constrained worldwide, and this situation is likely to continue for some time. Advanced economies are pre-purchasing multiple COVID-19 vaccine candidates to mitigate the risk of development failure.

Noted

d) **Note** in May Cabinet approved the COVID-19 Vaccine Strategy [CAB-20-MIN-0229.01] with the objective of ensuring access to a safe and effective vaccine to implement the Government's preferred immunisation strategy at the earliest possible time.

Noted

e) **Note** in August Cabinet established a tagged contingency of up to $600 million [CAB-20-MIN—382] for purposes including the advance purchase arrangements of potential COVID-19 vaccines, Cabinet also delegated purchase decisions to Joint Ministers.

Noted

f) **Note** in September Joint Ministers agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (briefing MBIE 202 –0662 refers).

Noted

g) **Note** earlier this week Cabinet increased the tagged contingency to $1,050 million and added the Minister for COVD-19 Response to the group of Joint Ministers with delegated authority to make purchase decisions [CAB-20-MIN-0508].

Noted

h) **Note** earlier this week Cabinet agreed that up to $75 million be allocated from Vote Official Development Assistance to support Pacific and global vaccine access, and that New Zealand should actively seek to purchase up to 360,000 additional doses of at least one suitable vaccine candidate specifically for Polynesia to be funded from within the allocation with the approval of delegated Ministers [CAB-20-MIN- 0504].

Noted

i) **Note** we have been assessing vaccine candidates prioritised by the Vaccine Taskforce against the purchase decision-making framework.

Noted

j) **Note** you have agreed to accept an offer from Pfizer Inc. for the purchase of 750,000 courses of an mRNA vaccine candidate for delivery early next year (briefing MBIE 2021-0996 refers); to enter into non-binding terms from Janssen Pharmaceutica NV for the purchase of five million courses of a viral vector vaccine for delivery in 2021 and 2022; and, to enter into a binding supply agreement with AstraZeneca Ltd for the purchase of 3.8 million courses of a viral vector vaccine for delivery in 2021.

Noted

k) **Note** there is an opportunity to purchase 5.36 million courses of Novavax Inc's vaccine candidate for delivery as early as the second quarter of 2021.

Noted

l) **Note** the negotiations for this purchase opportunity have been carried out with advice from legal and science experts. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

Noted

m) **Agree** to terms for the purchase of 5.36 million courses of Novavax Inc's COVID-19 vaccine candidate (the terms are attached in Annex One), at a cost of 9(2)(ba)(i), 9(2)(ba)(ii) (which includes provision of 9(2)(ba)(i), 9(2)(ba)(ii) to address the risk of foreign exchange rate fluctuations). Your agreement is subject to the Minister of Finance's agreement to grant an indemnity to Novavax Inc. and specified associated persons.

Agree / Disagree

n) **Agree**, if you agree to the recommendation in m), and the Minister of Finance agrees to grant the Novavax indemnity, that the Director-General of Health and the Minister of Finance sign the supply agreement on behalf of the New Zealand Government to give effect to the decision in m).

Agree / Disagree

o) **Agree**, if you agree to the recommendation in m), to draw down 9(2)(ba)(i), 9(2)(ba)(ii) from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' to purchase Novavax Inc's vaccine candidate.

Agree / Disagree

p) **Approve**, if you agree to the recommendation in m), the following changes to appropriations to provide for the decision in recommendation o) above, with a corresponding impact on the operating balance and net core Crown debt:

	$m - increase/(decrease)				
Vote Health Minister of Health	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**2024/25 & Outyears**
Non-Departmental Output Expenses:					
Minimising the Health Impacts of COVID-19	9(2)(ba)(i), 9(2)(ba)(ii)		-	-	-
Total Operating			-	-	-

Approve/ Not approve

q) **Authorise** the Minister of Finance and the Minister of Health to transfer any unspent 2020/21 funding in Vote Health agreed under the recommendation p) to the 2021/22 financial year, as required, with no impact on the operating balance and net core Crown debt across the forecast period.

Authorised/ Not authorised

r) **Agree** that the changes to appropriations for 2020/21 above be included in the 2020/21 Supplementary Estimates and that, in the interim, the increase be met from Imprest Supply.

Agree / Disagree

s) **Note** that Treasury officials will seek agreement of the Minister of Finance to the terms of an indemnity for Novavax Inc. and specified associated persons.

Noted

t) **Note** negotiation of final supply terms for advance purchase arrangements with Pfizer Inc. and Janssen Pharmaceutica NV are progressing and may be concluded before the end of the year.

Noted

Rt Hon Jacinda Ardern

Prime Minister

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

Hon Grant Robertson

Minister of Finance

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

Hon Dr Megan Woods

Minister of Research, Science, Innovation

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

Hon Chris Hipkins

Minister for COVID-19 Response

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

Hon Andrew Little

Minister of Health

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

Maree Roberts

Deputy Director-General, Ministry of Health

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

Dr Peter Crabtree

General Manager, Science, Innovation and International, MBIE

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

Background

Global demand for COVID-19 vaccines remains high

1. An unprecedented health crisis continues worldwide, and New Zealand's population remains entirely susceptible to COVID-19 due to our successful elimination strategy.

2. Our ability to recover from the COVID-19 pandemic and relax public health controls relies on the availability of safe and effective COVID-19 vaccines. The global demand for COVID-19 vaccines continues to be high, and capacity to manufacture successful vaccine candidates is heavily constrained worldwide. This constraint is expected to be the case for some time.

Ministers have previously agreed to a COVID-19 vaccine purchasing strategy and a framework to guide purchase decisions

3. In May, Cabinet agreed a purchasing strategy to support acquisition of COVID-19 vaccines [CAB 20-MIN-0382]. A portfolio approach is intended to manage a range of risks and provide safe and effective vaccines to choose from for early deployment as part of New Zealand's immunisation strategy. This improves the chances of acquiring vaccines that can support achieving population cover from COVID-19 in a timely manner. The construction of the portfolio therefore requires the selection of vaccine candidates that ensure diversity across technology platforms, vaccine characteristics, suppliers, and timeframes, and that are suitable for use in the Realm of New Zealand and other Polynesian countries.

4. In August, Cabinet established a tagged contingency of up to $600 million [CAB-20-MIN-382] in order to finance advance purchase agreements (APAs) of potential COVID-19 vaccines and to meet additional early costs of the Government's immunisation programme. Cabinet delegated purchase decisions to the Prime Minister, the Minister of Finance, the Minister of Research, Science and Innovation and the Minister of Health (Joint Ministers).

5. Joint Ministers have agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (briefing MBIE 2021 – 0662 refers). The application of the framework criteria is intended to ensure that APAs align with New Zealand's overall objectives for responding to COVID-19 and recognise that our decisions on advance purchasing will be made on the basis of early-stage information.

6. Earlier this week Cabinet agreed to increase the tagged contingency to $1,050 million to fund the purchase of COVID-19 vaccines [CAB 20-MIN-0508]. Also, the Minister for COVID-19 Response was added to Ministerial group authorised to make vaccine purchasing decisions.

7. Once concluded, APAs will commit New Zealand to the purchase of vaccines, conditional on successful clinical trials of the vaccine candidate and regulatory approval in New Zealand. Money spent on APAs will be lost if the development is unsuccessful, if the candidate is found to be unsuitable for deployment as part of the Government's preferred immunisation strategy, or if the supply is in excess of what is required under that strategy and cannot be on-sold. In the current global context, this is the cost of attempting to secure supply of vaccines that are still being developed.

8. In effect, the cost of COVID-19 vaccines includes the 'insurance premium' of pre-purchasing a portfolio that manages risk and provides sufficient options to implement our preferred immunisation programme. COVID-19 vaccines need to play a different role in New Zealand compared to countries with uncontrolled spread of COVID-19. That is because in the latter, even marginally effective vaccines that are administered to any proportion of their population will likely be an improvement on their status quo. In New Zealand's case we need to use the most effective vaccines, and aim for broad vaccination uptake, to reach the level of population cover that would support safely reconnecting with the world and moving away from more blunt and costly public health measures.

9. It is still too early to tell which vaccine will be ideal for New Zealand and Polynesian countries. It is also likely we will need a range of vaccines for different people, to achieve the broadest possible uptake. Along with the other uncertainties we are trying to manage, this is why we have adopted a portfolio approach and accepted that the actual cost of an effective vaccination programme will be more than the vaccines that may eventually be used in New Zealand's immunisation programme.

10. COVID-19 vaccine suppliers are requiring purchasers to provide them with indemnities so that both parties share the risks of accelerated vaccine development. In normal circumstances many of these risks can be covered by insurance, but in the case of COVID-19 vaccines, suppliers have told us this is not feasible.

11. Decisions to be taken later, including whether to use these vaccines in New Zealand, or whether to offer any vaccines to Polynesia, will depend on their suitability for deployment, either as part of New Zealand's immunisation strategy, or in Polynesia. More information, not yet available, such as final clinical trial results will inform these decisions.

12. Discussion with international counterparts and media announcements indicate a number of like-minded countries have reserved large quantities of a number of vaccine candidates through APAs in order to mitigate the risk that vaccine candidates could fail.

A purchase agreement with Novavax is key to building resilience in the 'core portfolio' of COVID-19 vaccines

13. We consider that the Novavax vaccine is a critical addition to our 'core portfolio', building resilience by reducing technology risk and being available in sufficient courses for wide population cover. It would add an established vaccine type, with a relatively early delivery date, that can be distributed using standard processes. Despite 9(2)(ba)(i), 9(2)(ba)(ii) some delivery risk, we are confident about the important contribution of this vaccine to our preferred portfolio. This opportunity compares very favourably to other opportunities we have considered, where clinical and negotiation outcomes are less promising.

14. All COVID-19 vaccines still carry development risk, and the 'ideal' vaccine is not yet available to buy. As outlined to Cabinet last Monday, in order to have high confidence of achieving the objective of acquiring sufficient safe and effective vaccines for timely use in New Zealand and Polynesia, our portfolio requires four vaccine candidates available in quantities to provide broad cover for the population. It should also include at least one candidate from the three main vaccine technology types (RNA, viral vector, and protein sub-unit). Countries using similar purchase frameworks to us have aimed to include at least one vaccine of each of these types. From information available now, four candidates represent a portfolio which we consider will have sufficient diversity to manage risks with respect to technology platform, vaccine characteristics, global supply constraints and failure to achieve timely regulatory approval (MBIE briefing 2021-1124 refers). The needs of the portfolio may change over time as more information is obtained.

15. From the vaccine candidates globally under development we have engaged with eight targeted vaccine suppliers. The COVID-19 Vaccine Strategy Taskforce have prioritised concluding negotiations with four of those suppliers by the end of the year: Pfizer Inc. (Pfizer), AstraZeneca Ltd (AstraZeneca), Janssen Pharmaceutica NV (Janssen) and Novavax Inc. (Novavax). Together these APAs will give us a promising 'core portfolio'. The composition of the portfolio aligns with the approach taken by other advanced economies through their APAs.

16. Information about these candidates is broadly promising and we do not have any major concerns from early clinical trial information. The table in Annex Two summarises the population coverage being sought, price and delivery times being negotiated for the four priority vaccine candidate targets.

17. In advancing negotiations with the four priority candidates we have relied on commercial, legal and expert scientific advice. We have assessed these offers against the vaccine purchase framework (see discussion from paragraph 26), and our negotiation priorities. We also received advice and endorsement from managers of financial portfolios on the overall approach to the construction of our vaccine portfolio.

18. Joint Ministers have agreed to terms to purchase 750,000 courses of an mRNA vaccine from Pfizer (briefing MBIE 2021-0996 refers) and five million and 3.8 million courses of viral vector vaccine candidates from Janssen and AstraZeneca respectively (briefings MBIE 2021-1195 and 2021-1537 refer). Novavax's offer is outlined below. Negotiations are at an advanced stage for the conclusion of definitive agreements with Pfizer and Janssen with whom we initially agreed heads of terms.

19. We have been negotiating the purchase of more courses of the Pfizer to secure sufficient additional vaccines for it to be the fourth broad coverage candidate required to complete the 'core portfolio'. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] We consider that the portfolio lacks sufficient broad coverage without the additional Pfizer doses. Therefore we will investigate the purchase of another high-volume candidate and continue to consider smaller purchases, including through the COVAX Facility.

The Novavax vaccine will add an established vaccine type to our portfolio and provide sufficient COVID-19 vaccines for broad population cover

20. Novavax has offered New Zealand 5.36 million courses of its vaccine candidate (known as NVX-CoV2373) for delivery as early as the second quarter of 2021. This is considered sufficient for broad population cover in New Zealand and Polynesia, factoring in 15 percent for wastage.

21. This vaccine will cost [redacted] course and, if successfully developed and delivered, will cost 9(2)(ba)(i), 9(2)(ba)(ii) (which requires a total of 9(2)(ba)(i), 9(2)(ba)(ii) to be set aside to include headroom to manage foreign exchange risk)[1]. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

22. The candidate adds an established vaccine type to the portfolio – it is a protein sub-unit and adjuvant vaccine administered intra-muscularly in two doses[2]. An adjuvant enhances the body's immune response and the combination is long established, and used, for example, in the hepatitis B vaccine in New Zealand. However, neither the component that provokes the immune response nor the adjuvant used in this vaccine are used in any licensed vaccines, so this technology platform is untested outside clinical trials.

23. The terms of Novavax's offer to sell the vaccines to New Zealand are contained in the legally binding supply agreement attached as Annex One. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

24. The Novavax offer is time-limited, and it is imperative that the supply agreement is concluded without delay because New Zealand's vaccine allocation is held temporarily from the global

[1] The sale price is denominated in USD and the vaccine costs 9(2)(ba)(i), 9(2)(ba)(ii) Using today's indicative NZD USD exchange rate of 0.6595 the estimated cost of each vaccine is [redacted] There is a foreign exchange risk because the price is denominated in USD, and the Treasury have recommended including headroom of [redacted] million to address that risk

[2] The candidate works by presenting an antigen, constructed using part of the COVID-19 virus, to the immune system. The antigen elicits an immune response to the disease.

allocation. We are therefore advising you on purchase decisions as each negotiation concludes. There is limited control over the sequence of purchases.

We recommend purchasing the Novavax COVID-19 vaccine candidate

25. We believe there is a strong rationale to sign the purchase agreement because:

- From very early information, the vaccine appears to provoke a good immune response and studies in non-human primates show that it has some potential to reduce transmission.
- This purchase would add an established and sought after vaccine type to our portfolio, increasing the technology diversity of the portfolio from two to three vaccine types. A protein sub-unit vaccine was identified by the Vaccine Taskforce as important for the portfolio and alternatives would not provide sufficient cover.
- The purchase is also for sufficient courses to achieve wide population cover. There is only one vaccine in the 'core portfolio' that could achieve this and there are no alternatives in the group prioritised by the Vaccine Taskforce that could provide wide population cover.
- While there are inherent risks to the delivery time of all vaccine candidates, delivery is expected to start from the second quarter of 2021. This is relatively early and likely to be comparable to delivery of the Pfizer vaccine. The supplier has an advanced plan for regulatory approval in the European Union which will assist with a timely process in New Zealand.
- It is expected to be straightforward to deliver using familiar cold chain systems.
- 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]
- We have negotiated terms that we believe are satisfactory, and are in line with global trends for COVID-19 vaccine advance purchase arrangements. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]
- Other advanced economies have purchased this vaccine candidate. Together, the USA, the UK, Canada, Japan, and Australia have arrangements to purchase over 270 million courses of this vaccine candidate[3]. The European Union is in preliminary talks. Many of these countries have used similar purchase frameworks to ours, using their experts to interrogate the early science results, trial designs and manufacturing programmes.
- The supplier is an inexperienced pharmaceutical supplier, and therefore the purchase carries a higher level of delivery risk than previously concluded agreements. However, we are confident that they will be able to manufacture at scale and deliver the vaccine.

[3] The USA has purchased 50 million courses, the UK has purchased 30 million courses, Canada has purchased 48 million courses, Japan has purchased 125 million courses, and Australia has purchased 20 million courses.

Overall, this vaccine appears to meet the purchase framework criteria

26. The vaccine purchase framework is outlined in Annex Three. It considers expected vaccine performance, expected availability and access, contribution to portfolio balance, and strategic approach. Vaccine performance considers criteria such as safety profile, effectiveness and ease of distribution across the population as a whole and to particular population groups. Availability and access considers factors such as confidence in production, contractual terms, geopolitical dynamics and international risks. In advance of full vaccine development and regulatory approval and in the absence of final data, the framework uses proxies to help inform choices.

27. We took a multi-agency approach in negotiations to strengthen the level of interrogation. We have taken advice from Bell Gully, as well as from an independent scientific and clinical review panel, to help inform our analysis of the offer and information about the vaccine candidate, the developer and the supplier. Overall, we consider that the criteria in the framework have been met to a satisfactory level. That analysis is discussed below, with further detail attached as Annex Four.

Application of vaccine purchase framework criteria

	Criteria	Importance	Assessment of criteria	Level of satisfaction of criteria
Performance	**Safety profile and effectiveness**	Critical	As confident as we can be from early information	✓ ✓ ✓ *
	Ease of distribution	High	There may be some issues with vaccine acceptance. Distribution is generally in line with norms	✓ ✓ ✓
	APAs with other countries	High	APAs concluded with similar countries	✓ ✓ ✓
Accessibility	**Production**	Critical	Reasonably confident in planned production	✓ ✓
	Contracting	High	Satisfactory contractual terms negotiated	✓ ✓ ✓
	International risk	High	International risk is medium	✓ ✓
	Comparable price offered to others	High	International price achieved	✓ ✓ ✓
Portfolio	**Portfolio fit**	Critical	Good fit with portfolio strategy	✓ ✓ ✓

Key: ✓ ✓ ✓ high satisfaction of criteria; ✓ ✓ moderate satisfaction of criteria; ✓ satisfaction of criteria; • criteria not met.

* From limited data. It will be essential to see data from phase III human trials for this candidate before drawing conclusions about its safety, immunogenicity and efficacy.

The candidate shows some promise in terms of performance, but only early stage data are available

28. Phase III trials are just beginning for this candidate and interim data are expected in the first quarter of 2021. As such, there is less information than was available for the other candidates already purchased. We will continue to monitor new information about safety and efficacy as clinical trial data becomes available, and we note that additional data about safety will be

available at the time decisions are made on whether to use the vaccine. Commentary from the science review panel provided on 8 November 2020 is attached as Annex Five. Novavax has not provided additional trial data since then so the commentary remains up to date. Specifically, in relation to two vaccine performance criteria this candidate shows some promise:

- Safety – Similarly to the other three candidates in the portfolio, this vaccine seems to have temporary side effects (such as headache, fatigue, and aches and pains), particularly after the second dose. While this could impact how well the vaccine is accepted, it may be possible to mitigate perception risks at the time of deployment through communications planned as part of the immunisation programme.
- There is little available data about the previous use of the adjuvant, which is only used in one other vaccine. As with other COVID-19 candidate vaccines, there is the potential for safety issues including disease enhancement after vaccination. However, before the vaccine is used, our regulatory approval process will determine if the vaccine is safe and effective.
- Effectiveness – This vaccine appears to provoke a strong immune response. However, there are no agreed immunological measures available to allow accurate comparisons between vaccines. There is no human efficacy data yet for this vaccine and studies are yet to be undertaken in children and adolescents under 18 years of age. However studies in primates suggest potential efficacy against transmission. This could have the potential to reduce the spread of COVID-19 if it is confirmed in human studies.

Deployment requirements are within general expectations for COVID-19 vaccines

29. The vaccine is distributed using 2-8 degree Celsius cold chain methods. This is standard for vaccines, including in the Pacific (however, volumes would be much greater than standard volumes). The developer is testing stability at ambient temperatures, which, if successful, could make point-of-use storage and distribution simpler and more fail-safe, including in Polynesia.

30. You have agreed to draw down $66.3 million from the tagged contingency to urgently purchase critical resources for the immunisation programme, including resources to support cold chain capacity around New Zealand, of the type needed to deploy this vaccine candidate (briefing HR 20201744 refers). The Novavax candidate has been purchased by other similar countries.

31. An important proxy indicator of vaccine performance is the extent to which APAs have been concluded with other countries who have greater resources to vet candidates and use similar purchase frameworks to ours. Novavax has concluded arrangements with the USA, the UK, Canada, Japan, and Australia for the sale of over 270 million courses. The European Union is in preliminary talks for 50 million courses.

If the clinical trials are successful, there is reasonable confidence that Novavax will be able to supply the vaccine to New Zealand

32. Relative to the suppliers of the other target candidates, Novavax, a late-stage biotechnology company, is smaller, less well-resourced and has less experience in the global pharmaceutical market. It has no prior experience in the New Zealand pharmaceutical market. They plan to produce one billion courses of the vaccine for global distribution from mid-2021 by re-establishing their global supply chain and outsourcing manufacturing arrangements.

33. Novavax has secured US$ 2 billion in funding from Operation Warp Speed (a United States' government programme) and the Coalition for Epidemic Preparedness Innovations (CEPI) for late-stage clinical development and to establish large-scale manufacturing. Novavax has engaged the Serum Institute of India to manufacture one billion doses in 2021. These

international partnerships provide assurance of Novavax's ability to develop and manufacture the vaccine.

34. Novavax has indicated that New Zealand's vaccines are likely to be manufactured in [redacted] and [redacted] with the majority of the drug substance coming from the [redacted] and fill and finishing carried out in [redacted] Although individually [redacted] there is some risk from fragmentation, as we are relying on more countries to have favourable export settings than with other candidates. We do not consider that this risk is sufficient to preclude the proposed purchase.

Delivery schedules are not certain, deliveries may be delayed and there is no guarantee of a vaccine

35. Novavax has confirmed its expectation that New Zealand will receive vaccines from the second quarter of 2021, with the bulk of deliveries arriving in the third and fourth quarters of 2021. However, the terms of the purchase agreement do not create fixed delivery obligations. This is common to all candidates because vaccines are not yet approved for use in New Zealand, trials are ongoing, and manufacturing scale-up has not been completed. Factors that will have an impact on the eventual delivery schedule include when the supplier can provide data to Medsafe for assessment.

The vaccine [redacted] is not expected to have significant additional administration costs

36. [redacted]

37. [redacted] doses provided to Polynesia will be funded from the $75 million Official Development Assistance envelope approved by Cabinet in December to support Pacific and global access to vaccines.

38. The COVID-19 Immunisation Strategy and Programme [CAB-20-MIN-0509], led by the Minister of Health provides an 'operational blueprint' for rolling out COVID-19 vaccines to ensure the best outcomes.

39. Distribution and deployment costs are likely to be within the normal range for COVID-19 vaccines. Novavax is testing the stability of the vaccine at ambient temperatures, and if it is found to have this characteristic the resources needed to store and distribute the vaccine, and risk of storage condition failures, could be reduced, especially for hard to reach areas and in the Pacific.

The vaccine could play an important role in the portfolio to provide broad population cover and limit the risk of technology failure

40. The Novavax vaccine is the only protein sub-unit candidate being considered for the portfolio. This is one of the three vaccine types that we expect the 'core portfolio' to contain in order to mitigate development risk. Unlike mRNA vaccines (Pfizer's candidate), and viral vector vaccines (Janssen's and AstraZeneca's candidates), protein sub-unit vaccines are a well-established vaccine type, albeit the exact technology in this vaccine is unlicensed.

41. Similar to Janssen's and AstraZeneca's vaccines, the Novavax vaccine could offer broad population cover. This provides significant benefit to the portfolio as it reduces the need for multiple candidates to succeed before we are able to achieve wide population cover. On the

other hand, the vaccines that could offer broad coverage all have different drawbacks that could prevent their widespread use. This is why we are building a portfolio of vaccines: to maximise options for the immunisation programme, and increase our chances of having safe and effective vaccines for population-wide deployment. This reflects the approach taken by other countries using similar purchase frameworks to ours.

42. Early non-human primate studies suggest that there is potential for the Novavax candidate to reduce infectiousness. The developers have indicated that there is a potential for the vaccine to be stable at room temperature. There would be significant portfolio benefits in terms of effectiveness and ease of deployment if these characteristics are confirmed.

43. Not purchasing the Novavax candidate would have the following implications for the portfolio:

- We will need to consider purchasing two different vaccine candidates to build the core portfolio of four candidates with wide coverage. There are no other protein-based vaccines currently in late-stage clinical trials. Sanofi/GSK is developing a protein-based vaccine but is unwilling at this stage to enter into a bilateral agreement (though some courses may become available through the COVAX Facility).
- If we did not pursue an alternative to the Novavax vaccine candidate, the portfolio would only have two vaccine candidates with wide population coverage – both using viral vector technology. Broad cover using only one of the three main vaccine types would result in little optionality for the immunisation programme. This is particularly because the Janssen vaccine candidate is scheduled to arrive later than the AstraZeneca and Pfizer candidates.

9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

44. In August the previous Minister of Foreign Affairs agreed in principle that Official Development Assistance (ODA) could be used to reimburse the cost of vaccines passed on to Polynesian countries.

45. Earlier this week, Cabinet agreed that up to $75 million be allocated from Vote Official Development Assistance to support Pacific and global access to COVID-10 vaccines, and that New Zealand should actively seek to purchase up to 360,000 additional doses of at least one suitable COVID-19 vaccine candidate specifically for Polynesia. The purchase should be funded from within that allocation [CAB-20-MIN-0504].

46. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

Opportunities for local manufacture of vaccines was sought as a means of mitigating supply risks

47. The supplier has indicated that it has sufficient manufacturing capacity to supply vaccines for New Zealand. Therefore local manufacturing options do not need to be considered and are not an option.

It is not clear if the vaccine will be available through the COVAX Facility

48. Joint Ministers agreed to purchase COVID-19 vaccines through the COVAX Facility for up to 50 percent of New Zealand's and the Realm's adult population and to join the Facility through its Optional Purchase Arrangement (briefing MBIE-2021-0858 refers). Under this arrangement, we will receive 'purchase opportunities' (an option to purchase) for vaccine candidates as they are added to the Facility's own portfolio.

49. The COVAX Facility is still negotiating with vaccine developers, and there are a range of details (such as pricing and volumes) to be finalised before we are offered final purchase options.

50. The receipt of CEPI funding by Novavax is a strong indicator that the vaccine candidate may become available through the COVAX Facility. However, New Zealand is unlikely to need to take up the offer if the attached purchase agreement is concluded.

Commercial considerations

51. We have taken legal and commercial advice from Bell Gully and others during the negotiation of terms with Novavax. PHARMAC has also been involved in the negotiations. We consider that a good outcome has been achieved. Important concessions such as i9(2)(ba)(i), 9(2)(ba)(ii) and obtaining the ability to resell or pass on vaccines to others, have been achieved.

52. Overall, we consider that reasonable terms have been negotiated, and mutually acceptable outcomes have been achieved where New Zealand had to make concessions.

53. The terms in the proposed supply agreement are in line with the negotiating priorities agreed with the Vaccine Taskforce, and we understand they are in line with commercial expectations, with the exception of the indemnity. An outline of how the terms compare to negotiating priorities is included in Annex Six.

54. In summary:

9(2)(ba)(i), 9(2)(ba)(ii)

Novavax and specified associated persons are seeking an indemnity from the Crown

55. All COVID-19 vaccine suppliers are requiring purchasers to provide indemnities to protect them against a range of risks. In normal circumstances many of these risks can be covered by insurance, but in the case of COVID-19 vaccines pharmaceutical companies have told us that

this is unfeasible. A robust regulatory approval process (see discussion on regulatory approval below) is an important mitigation of the risk to the Crown of providing the indemnities.

56. Novavax and specified associated persons are seeking an indemnity because:

- As with all COVID-19 vaccine development, Novavax is developing the vaccine in accelerated clinical trials that are less likely than non-accelerated trials to detect uncommon adverse effects or possible contraindications. COVID-19 vaccine trials are expected to be shorter and have fewer trial subjects than ordinary pharmaceutical development which will reduce the known safety profile of the vaccine.
- Novavax perceives a risk of broader claims associated with the use, deployment and administration of the vaccine, and with the potential conduct of the Crown in relation to the APA.

57. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

58. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

59. [redacted]

60. We will provide a business case to the Treasury on the indemnity provision negotiated. The Minister of Finance can give an indemnity under section 65ZD of the Public Finance Act 1989 (PFA), if it appears to the Minister to be necessary or expedient in the public interest to do so. On the basis of the business case, the Treasury will advise the Minister of Finance on whether the indemnity may be considered to meet the public interest test in the PFA. Your agreement to the terms of the supply agreement will be subject to the Minister of Finance's agreement to grant the indemnity. The Sovereign in Right of New Zealand acting through the Minister of Finance is a contracting party to the agreement with respect to the provisions in the agreement that relate to the indemnity.

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

61. If you agree to purchase Novavax's vaccine candidate, a draw-down of 9(2)(ba)(i), 9(2)(ba)(ii) from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' will be required to fund the purchase price for 5.36 million vaccines and headroom to address foreign exchange risks. A draw-down is recommended at this stage because, while the final payments for the purchase will be contingent on the successful development of the vaccine, the execution of the supply agreement indicates a clear intention to purchase the vaccines.

62. The draw-down would enable the following payment to be made:

Payment	Timing	Cost (NZ$)
Advance payment	9(2)(ba)(i), 9(2)(ba)(ii)	9(2)(ba)(i), 9(2)(ba)(ii)
Delivery payments	From second quarter of 2021	
Total		

9(2)(ba)(i), 9(2)(ba)(ii)

63. 9(2)(ba)(i), 9(2)(ba)(ii)

Regulatory approvals will be a separate process

64. No COVID-19 vaccine can be used as part of an immunisation programme within New Zealand until it has received regulatory approval from Medsafe (and the Environmental Protection Authority where relevant). We understand that Novavax is in advanced discussions with the United Kingdom and European regulators. The supplier has had preliminary discussions with Medsafe. The supplier has an advanced plan for a progressive regulatory approval process in the United Kingdom and the European Union which will assist with a timely process in New Zealand.

65. The time required to achieve regulatory approval is to a large extent dependent on the timeliness and quality of the information provided by suppliers to regulators.

66. Medsafe is working to ensure there is an efficient approvals process in order to evaluate a number of concurrent COVID-19 applications, while ensuring that vaccines meet acceptable standards for efficacy, safety and quality. The timeliness and quality of the information provided by suppliers to Medsafe can influence the length of the process for regulatory approval.

67. We understand the supplier is aware of their need to engage with the Environmental Protection Authority.

Communications and publicity

68. There is strong public interest in the efforts of pharmaceutical companies to develop effective and timely COVID-19 vaccines, and also in which countries would likely have access to vaccines once they have been developed and approved for use.

69. Subject to your agreement to execute the supply agreement and the Minister of Finance's agreement to provide an indemnity, and following discussions with advisers in your offices, we propose to announce this, and the agreement with AstraZeneca, at a media event led by the Prime Minister in Auckland on 17 December.

Next steps

70. Subject to your agreement to the supply agreement, and the Minister of Finance's agreement to provide an indemnity to Novavax, the Director-General of Health and the Minister of Finance will execute the supply agreement on behalf of New Zealand.

71. The advance payment will be made within 30 days of the conclusion of the supply agreement.

72. We will report to you over the next few weeks on the conclusion of APAs with Pfizer and Janssen.

Annexes

Annex One: 9(2)(ba)(i),9(2)(ba)(ii)

Annex Two: 9(2)(ba)(i),9(2)(ba)(ii)

Annex Three: Summary of vaccine purchase framework.

Annex Four: Summary of vaccine purchase framework analysis.

Annex Five: Science Review Panel commentary.

Annex Six: 9(2)(ba)(i),9(2)(ba)(ii)

Annex Four: Summary of vaccine purchase framework analysis

Application of vaccine purchase decision making framework to the Novavax supply agreement

Purpose

This document captures information from negotiations, publicly available sources, advice from experts, and confidential information from trusted sources to apply the vaccine purchase framework to the draft supply agreement negotiated with Novavax Inc. (Novavax). Meeting the criteria in the framework informs the decision to enter an agreement with the supplier to purchase their vaccine candidate. As well as being one of the priority vaccine candidates, the framework criteria are vaccine performance, availability and access, and contribution to portfolio balance.

Process

The New Zealand Vaccine Taskforce has prioritised Novavax's vaccine candidate within the top four prospects for an APA (Advance Purchase Agreement). The candidate, supplier and supply agreement have been assessed against the criteria in the purchase decision-making framework and the negotiation priorities agreed to by the Taskforce.

Overall assessment

- Performance: Only very early stage information about safety and efficacy is available, Phase 3 clinical trials have recently commenced. As with other vaccine candidates the vaccine is reactogenic and has the potential for safety issues including disease enhancement after vaccination. However, it appears to provoke a good immune response, and studies in non-human primates show that it has some potential to reduce transmission. The manufacturer has successful experience in developing and trialling vaccines. The candidate has been purchased by a number of advanced economies using similar purchasing frameworks to ours. It is expected to be straightforward to deliver using familiar cold chain systems. Potential for distribution at ambient temperatures is also being tested.
- Availability and access: The contractual terms are reasonable and despite some delivery risks (associated with a fragmented supply chain), there is confidence in the supplier's ability to manufacture and deliver. The development has been funded both by Operation Warp Speed (OWS) and by the Coalition for Epidemic Preparedness Innovations (CEPI). 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]
- Contribution to portfolio balance and strategic approach: It will add an established vaccine type to the portfolio in sufficient numbers to provide wide population cover. A protein sub-unit vaccine is one of three main vaccine types sought for the portfolio. There are no alternatives in the group

of vaccine candidates prioritised for investigation and negotiation by the Vaccine Taskforce that will contribute a protein sub-unit vaccine in sufficient quantities, or an alternative vaccine type in sufficient quantities to provide wide population cover.

Key to achievement of framework criteria:

- ✓✓✓ Criteria achieved with high confidence, based on current information.
- ✓✓ Reasonable confidence that criteria will be met, and nothing to indicate that criteria will not be met.
- ✓ Criteria could be achieved, but there are issues to be resolved.
- ✗ Criteria is not achieved, or will not be achieved.
- ◆ No indicators available at the time decisions are made.

Supplier – Novavax Inc.			Vaccine candidate: NVX-CoV2373
Platform and description			Platform: Recombinant virus nanoparticle vaccine (protein sub-unit). Adjuvant: Matrix-M1 (a saponin-based adjuvant). Novel technology: Recombinant virus nanoparticle vaccine, Matrix-M1. Antigen production: Insect-cell expression system (baculovirus *S. frugiperda* system). The candidate is a recombinant SARS-CoV-2 nanoparticle vaccine, constructed from the full-length spike glycoprotein.
	Importance	**Fit with framework criteria**	
Priority candidate groups: A, B, C **Confidence in priority ranking**	Should be in Group A	Group A	***The candidate has high priority within Group A*** Criteria for inclusion within group A are reputable supplier, with potential for supply to New Zealand that is suitable for use in the immunisation programme in 2021 and 2022.
Vaccine performance			*What we can assess in absence of full information from clinical trials*
Track record and reputation of the vaccine developer and key scientists (including signals from regulators and CEPI)		✓✓✓	***The developer has experience in developing vaccine technology, but is less experienced commercialising vaccines***

			Novavax is a late-stage biotechnology company that promotes improved health globally through the discovery, development, and commercialisation of innovative vaccines to prevent serious infectious diseases. Novavax has broad experience in developing and trialling various vaccines technologies. The company promotes itself as a leading innovator of recombinant vaccines. Recent success has been in their most recent RSV vaccines, which are yet to be brought to market. Earlier versions have been halted due to severe adverse events during trials. Novavax is new to manufacturing, commercialising and supplying vaccines. The company has no history of supplying pharmaceutical products to the New Zealand market and is new to New Zealand regulatory requirements. ***The supplier is not as well resourced as other suppliers we have purchased from*** The company is relatively small compared to other target suppliers, and has small staff numbers. They appear to be contracting in resources to address their capability issues. ***There is strong support from international funders*** The supplier has secured US$ 2 billion in funding from OWS (a United States' government programme) and CEPI to fund late stage clinical development and to establish large-scale manufacturing. Novavax has engaged with the Serum Institute of India to manufacture one billion doses in 2021. These international partnerships demonstrate confidence in Novavax's ability to develop and manufacture the vaccine.
APAs concluded with other countries		✓✓✓	***Novavax has concluded APAs with a number of countries that use similar purchase frameworks to ours*** Other advanced economies include this vaccine candidate in their vaccine portfolios:

			• United States (US) 25 million courses, United Kingdom (UK) 15 million courses, Canada 24 million courses, Japan 62 million courses, Australia 20 million courses. • The European Union is in negotiations with Novavax for purchase of vaccines and has agreed a regulatory approval process. Comparator countries have used similar frameworks to ours, using their experts to interrogate the early science results, trial designs, and manufacturing programmes. The 'top list' of countries with similar safety and effectiveness requirements are: • Australia, the European Union (European Medicines Agency – EMA), UK (Medicines and Healthcare products Regulatory Agency -MHRA), US (Food and Drug Administration-FDA), Canada, and Switzerland (SwissMedic). Singapore is also comparable in terms of benefit risk assessment.

Clinical trials			**Clinical trials**
			
			• **Phase 1** Aus adults N=131, 18-59 years healthy participants – began in August.
			• **Phase 2** Aus/US adults N=1500 (n=750 >60 years): This clinical trial has been conducted across up to 40 sites in Australia and the US Began in August.
			• **Phase 2b** South Africa N=4500, 18-65 years (n=240 HIV+). Began in August.
			• **Phase 3** placebo-controlled trial in UK underway – began in September
			  ○ N=9000, 18-84 years (n=400 inactivated influenza vaccine co-admin).
			  ○ The trial will include those aged 18-84 years of age and people with stable chronic medical disorders, but will exclude pregnant/lactating women.
			  ○ The trial protocol calls for unblinding of data once 152 participants have achieved mild, moderate or severe endpoints.
			  ○ The company announced recently that it is looking to increase up to N=15,000 and expects to be fully enrolled by end of November.
			  ○ Novavax has noted that, dependent on "the overall COVID-19 attack rate", interim data are expected as early as Q1 2021 and are presumed to serve as the basis for regulatory approval globally.
			• **Phase 3** US and Mexico N=30,000 adults > 18 years.

			○ Novavax expects this clinical trial to begin by end of November. ○ Novavax notes there will be proportional representation among diverse populations most vulnerable to COVID-19, distributed across race/ethnicity, age and those living with co-morbidities. ○ The trial protocol will be posted on Novavax' website upon initiation. **Also to note** • Novavax plan on conducting a trial in 12-18 year olds, safety and immunogenicity beginning in Q1 2021.
Safety • Aggregate and non-aggregate (taking into account population groups) • Side effects and adverse reactions	Critical	✓✓✓ From what is possible to know with very early stage information	***From very early stage information, the vaccine candidate, like other candidates in the portfolio so far, is reactogenic.*** The information below is drawn from the Science and Clinical Review Panel commentary and overview[1].A Phase 1 clinical trial (in 18-59 year old healthy participants) showed that this vaccine is reasonably reactogenic (temporary side effects such as headache, fatigue, and aches and pains were noted). This is similar to what has been observed for the other three candidates in the current portfolio. The vaccine is particularly reactogenic after a second dose (where moderate or severe systemic events were seen in around 43% of vaccinated participants). However, this group is very small so it is difficult to extrapolate the data with confidence. There is little available data about the previous use of the adjuvant, which is only used in one other vaccine. As with other COVID-19 candidate vaccines, there is the potential for safety issues including disease enhancement after vaccination. It is too soon to make judgements on any other aspect of safety. Phase 3 data, when available, will be critical to this analysis.
Effectiveness • Aggregate and non-aggregate	Critical	✓✓✓ From what is possible to know with very	***From very early information, the vaccine appears to provoke a good immune response and studies in non-human primates show that it has some potential to reduce transmission***

[1] From Commentary and Overview, both dated 8 November 2020. Novavax has not provided additional trial data since then so the commentary remains up to date.

		early stage information	The information below is drawn from the Science and Clinical Review Panel commentary and overview[2]. This vaccine appears to be highly immunogenic (antibody response) when compared to convalescent sera (but it is not clear if immunogenicity assays are comparable to those used by other vaccine developers, and whether it will be possible to compare immunogenicity across vaccines). Cell-mediated immunity data were shown for only a few participants, but the response was T helper cell 1 dominated (a positive indication). Data from studies using non-human primates suggest potential for reduced infectiousness (not just disease) as reduced/absent viral replication was seen in the upper respiratory tract. If demonstrated in humans, this would have the potential to reduce transmission, and could therefore be an important factor in the choice of vaccination strategies. The developers consider this to be a two-dose vaccine (given the boosting seen after a second dose). 9(2)(ba)(i), 9(2)(ba)(ii) The adjuvant has been used in the Nanoflu vaccine, but there is no published data (journal articles or on trial registry platforms) available from Phase 3 trials for previous use. 9(2)(ba)(i), 9(2)(ba)(ii) This antigen is produced in insect cells which results in a slightly different glycosylation profile to that seen in mammalian cell systems. The developer states this is a benefit as glycosylation can mask B-cell responses and therefore insect cell production may have an immunogenicity benefit. Cervarix, a highly effective HPV vaccine, is also produced using an insect-cell antigen production system. There is no reason to anticipate, based on current knowledge that insect-cell glycosylation would have any adverse impact on efficacy.
Ease of distribution:	High	✓✓✓	***The candidate is expected to be straightforward to deliver using familiar cold chain systems***

[2] Both dated 8 November 2020. Novavax has not provided additional trial data since then so the commentary remains up to date.

			The vaccine can be transported and stored using 2-8 degree Celsius cold chain methods. This is standard for vaccines, including in the Pacific (however, volumes would be much greater than standard vaccine volumes). The developer is testing stability at ambient temperatures (6-8 hours without preservative in a 10-dose vial) which, if successful, could make point-of-use storage and distribution simpler and more fail-safe, including in Polynesia. It could also support mass vaccination. No thermostability data were presented. The presentation is expected to be in a suspension (possibly 10 doses/vial), but this is not yet certain. Shelf life before and after vial opening is not yet known, 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] The latter two logistical challenges are common to all vaccines. There is also uncertainty around the rigidity of the timing between doses. Novavax noted in negotiations that they are continuing to collect data with the intention of investigating shelf life and expect that, by Q2 2021, that shelf life will be determined to be longer than six months. *Administration:* • 2 dose regimen, 21 days apart, intramuscular delivery. • 5 micrograms of antigen, dispensed in multi-dose vial, with no preservative. *Requirements in the Pacific:* • If stability studies show that this vaccine is stable at ambient temperatures, this would be a major advantage for use in the Pacific. More data are needed before this can be confirmed. *Vaccine acceptability:* • The lack of a preservative is likely to help with vaccine acceptability. • Other positive factors are that it is unlikely to be a genetically modified organism and that it is not derived from human cell lines. • The Science and Clinical Review Panel have noted the vaccine being a new platform and adjuvant as a possible risk (i.e. issue that might affect acceptability to the public in addition to safety and efficacy). *Transport logistics:*

			9(2)(ba)(i), 9(2)(ba)(ii)
Availability and access			
Production: • Confidence in developer • Reliability of supply chains for raw materials • Capacity (including domestic manufacturing and flexibility) • Delivery schedules • Technology platform • Licensing arrangements Regulatory issues	Critical	✓✓	***There is confidence in Novavax's ability to re-establish its production and scale up for manufacturing*** • Novavax is planning annual production capacity of over two billion doses (1 billion courses) starting mid-2021. This includes production at the Serum Institute in India. • Novavax has its own manufacturing capacity, including a recently acquired plant in the Czech Republic with the expected capacity to produce a billion vaccine doses per year. • There are manufacturing and supply agreements in Japan, South Korea, the United States, and the United Kingdom. There are recent media reports of production planned in Belgium. • Trial vaccine manufacturing was contracted out to Emergent Biosolutions, who are also producing AstraZeneca and Janssen COVID-19 vaccines. • While protein sub-unit vaccines are an established type of vaccine, the technology is still novel, which poses an element of risk, as with any other COVID-19 vaccines. • Scale up may be challenging, as the company is small and does not have previous experience in large scale production. ***There may be some supply-chain risk because of fragmentation of the manufacturing process to different sites*** • Novavax expect to manufacture New Zealand's vaccines in Spain and South Korea with the majority of drug substance originating from their proprietary plant in the Czech Republic. Fill and finish will occur at a few sites in Germany. • The fragmentation of the supply chain could lead to production risks. • 9(2)(ba)(i), 9(2)(ba)(ii)

			Delivery schedules are to be confirmed, but are relatively early 9(2)(ba)(i), 9(2)(ba)(ii) ***Regulatory issues*** • 9(2)(ba)(i), 9(2)(ba)(ii) of recruiting for their Phase 3 pivotal (for licensure) trial (and a 2b trial that will also collect efficacy data). • Novavax are in advanced discussion with licensing authorities, particularly the MHRA. Dossiers are likely to be submitted to MHRA and EMA (European regulator) first. • Novavax has indicated that it will provide information to New Zealand regulators in a rolling abbreviated process following submission to European and United Kingdom regulators. • Some aspects of this vaccine are new (adjuvant, nanoparticle technology). There is resemblance to earlier vaccine platforms (essentially an adjuvanted protein-subunit vaccine, but with a new adjuvant and the proteins presented as a nanoparticle). It may therefore be less complex to obtain regulatory approval than, for example, mRNA vaccines. • Novavax have confirmed that vials would be labelled in English and have provided specifications within the purchase agreement.
Contracting: • Type of purchasing agreement	High	✓✓✓	***The purchase agreement is a full supply agreement*** • Commercially acceptable terms have been negotiated.

• Partnership with other countries
• Options to manufacture
• COVAX implications
			• See separate business case for discussion of indemnity for Novavax and specified associated persons.
			
			Novavax has international partnerships that demonstrate confidence of others in its ability to develop and deliver a vaccine
			• Novavax has secured US$2 billion in funding for its global coronavirus vaccine program, including through
			  • their engagement with CEPI (for US$388 million in funding for vaccine development and manufacturing[3]
			  • engagement with United States through OWS (for US$1.6 billion in funding)[4]
			  • engagement with Serum Institute of India to manufacture one billion doses in 2021[5].
			
			Opportunities for local manufacture of vaccines was sought
			9(2)(ba)(i), 9(2)(ba)(ii)
			
			Novavax vaccines may become available through the COVAX Facility
			CEPI funding could be an indicator of future availability through the COVAX Facility.

International risk assessment: • Health, economic and social impacts of pandemic (impacts on demand and availability). • State support for development and manufacturing.	High	Medium risk	***Although this purchase carries some production and delivery risk because of fragmented supply chains, it is not high enough to preclude entering the arrangement[6]*** 9(2)(ba)(i), 9(2)(ba)(ii)

[3] https://ir.novavax.com/news-releases/news-release-details/novavax-receive-388-million-funding-cepi-covid-19-vaccine
[4] https://ir.novavax.com/news-releases/news-release-details/novavax-announces-16-billion-funding-operation-warp-speed
[5] https://ir.novavax.com/news-releases/news-release-details/novavax-announces-covid-19-vaccine-manufacturing-agreement-serum
[6] International risk assessment dated December 2020 from Ministry of Foreign Affairs and Trade for the New Zealand CVOID-19 Vaccine Taskforce.

• Sovereign hoarding. • US election. • COVAX commitments.			There is some distributional risk, and otherwise low reputational and geopolitical risk. These international risk considerations do not preclude purchase of this candidate, subject to ongoing monitoring to ensure adequate measures are in place to mitigate supply chain and distributional risks.
Number of courses of vaccine being purchased		✓✓✓	***Sufficient vaccine numbers have been agreed to provide wide population cover for New Zealand and for Polynesia*** • Novavax has agreed to provide 10,720,000 doses (5.36m courses). • This constitutes full population coverage for New Zealand and Polynesia and includes capacity for 15% wastage. • 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]
Cost per course		✓✓✓	***A satisfactory fixed price has been negotiated. It is at the higher end of the range of COVID-19 vaccines*** • This vaccine will cost around 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] • Total price is 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] million to be set aside to include headroom to manage foreign exchange risk). 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

Contribution to portfolio balance			
Diversity of vaccine platforms (proxy for immunological response)		✓✓✓	**The vaccine increase the technology diversity of the portfolio from two types to three, the diversity of candidates that can be used for wide population cover would increase from one to two** The vaccine candidate is classified broadly as a protein subunit, which is an established vaccine type. The recombinant virus nanoparticle vaccine and adjuvant (Matrix-M1 / a saponin-based adjuvant) are new technology. The vaccine type is one of the three identified by the taskforce that should be included in the portfolio. The candidate is the first protein sub-unit vaccine in the portfolio. The only other vaccines in the portfolio that can provide wide-population cover are viral vector vaccines (which is a more novel, and therefore less proven vaccine type). Comparator countries have sought to include at least one protein sub-unit vaccine in their vaccine portfolios. Relatively early delivery timeframe adds to the temporal optionality of the portfolio – particularly for immunisation in the second quarter of 2021. The potential for reducing transmission and potential for stability at ambient temperatures increases diversity in vaccine characteristics that could improve the way vaccines are used in the immunisation programme.
Diversity of suppliers		✓✓✓	***Improves the diversity of suppliers in the portfolio*** New supplier to portfolio. New location for manufacturing.
Equitable population coverage (including the Pacific)		✓✓✓	***The number of vaccines secured in the proposed agreement is sufficient for wide population cover in New Zealand and Polynesia*** • 5 million for New Zealand, 0.36 million for the Pacific, (includes capacity for 15% wastage).

Early access/Delivery timeframes		✓✓✓	***Delivery schedules are not certain, but the expected delivery timeframes are relatively early and suitable for an immunisation programme in 2021 and 2022*** • Delivery is expected to start 9(2)(ba)(i), 9(2)(ba)(ii) . Delivery schedule in doses per quarter, as noted in the agreement are: 9(2)(ba)(i), 9(2)(ba)(ii)

Other matters not part of the framework analysis		
Suitability for different population groups		Unlikely to be able to determine this at the time decisions are made.
Duration of immunity		Unlikely to be able to determine this at the time decisions are made.
Multi-lateral or bilateral		Bilateral.
APAs concluded by New Zealand		• Pfizer Inc. for the purchase of 750,000 courses of an mRNA vaccine candidate for delivery early next year • entered into non-binding terms from Janssen Pharmaceutica NV for the purchase of five million courses of a viral vector vaccine for delivery in 2021 and 2022 • binding supply agreement with AstraZeneca Ltd for the purchase of 3.8 million courses of a viral vector vaccine for delivery in 2021 (awaiting execution).

10 December 2020

Annex Five: Science Review Panel commentary

COVID-19 Vaccine Candidate Science Review Panel Commentary

Novavax COVID-19 candidate vaccine

8th November 2020

Novavax presented their candidate adjuvanted recombinant virus nanoparticle vaccine to the Science Review Panel on 13th October 2020. Both the antigen-bearing nanoparticle and the adjuvant are novel (no licensed vaccines use these technologies), so this platform is untested outside clinical trials. However, the antigen on the nanoparticle is a protein sub-unit, and adjuvanted sub-unit vaccines are long established. A phase 1 clinical trial (in 18-59yo healthy participants) showed this vaccine is reasonably reactogenic, especially after a second dose (where moderate or severe systemic events were seen in around 43% of vaccinated participants). The vaccine appears to be very immunogenic. Robust neutralising antibody responses occurred after 2 doses and even the lowest responses in vaccines were similar to that in non-hospitalised but symptomatic COVID-19 patients. Challenge studies (where non-human primates were dosed with the virus) showed both reduced virus replication in the lungs and a potential reduction in infectiousness (via reduced viral replication in the upper respiratory tract).

A pivotal, phase 3 placebo controlled trial is underway in the UK with 9000 participants. The trial will include those aged 18-84 year old and people with stable chronic medical disorders, but will exclude pregnant/lactating women. Efficacy outcomes will be symptomatic COVID-19 disease and safety outcomes will be followed up for 386 days in this trial. It is not clear whether recruitment and monitoring in phase 3 trials will be continued if efficacy endpoints are achieved early. Continued recruitment and monitoring will be important in order to obtain important safety data. Further studies will be conducted in the USA and South Africa (including 240 HIV infected participants). Studies in adolescents (<18y) will hopefully be conducted from early 2021.

This vaccine is being tested as a 2-dose vaccine, and will be presented in multi-dose vials (probably 10 doses per vial). It will be transported and stored at 2-8°C which is in line with the NZ standard cold chain for vaccine distribution. There was a suggestion from the developer that this vaccine could theoretically be stable at room temperature (as may some other candidate vaccines, if tested) but there are currently no data available to confirm this. Testing on stability at room temperature is underway, and if stability without reliable refrigeration is demonstrated, this will have advantages for distribution in the Pacific. As is likely to be the case for many candidate vaccines, current testing includes only those older than 18y and initial licensure is unlikely to include children. Data from a small number of rhesus monkeys suggest a potential effect on infectiousness (not just disease). If demonstrated in humans, this could offer a wider choice of vaccination strategies than for several other vaccines. However, substantially more data are needed before it is known if an effect on infectiousness will occur.

Novavax are aiming to produce 2 billion doses of vaccine annually from mid-2021 but has global commitments with this vaccine. The process of securing doses and obtaining estimated delivery dates to New Zealand is currently in progress with the developer.

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

MINISTRY OF HEALTH
MANATŪ HAUORA

BRIEFING

Purchase of COVID-19 vaccines from AstraZeneca Ltd

Date:	3 December 2020	**Priority:**	Urgent
Security classification:	Sensitive	**Tracking number:**	2021-1537

Action sought

	Action sought	Deadline
Rt Hon Jacinda Ardern **Prime Minister** Hon Grant Robertson **Minister of Finance** Hon Dr Megan Woods **Minister of Research, Science and Innovation** Hon Andrew Little **Minister of Health**	**Agree** to terms to purchase 3.8 million courses of a vaccine against COVID-19 from AstraZeneca Ltd.	7 December 2020
Hon Chris Hipkins **Minister for COVID-19 Response** Hon Nanaia Mahuta **Minister of Foreign Affairs**	**Note** contents of the paper	None

Contact for telephone discussion (if required)

Name	Position	Telephone	1st contact
Poppy Haynes	Manager, COVID-19 Vaccine Purchase, MBIE	9(2)(a)	✓
Maree Roberts	Deputy Director-General, System Strategy & Policy, MoH	9(2)(a)	
Bhagee Ramanathan	Principal Policy Advisor, MBIE	9(2)(a)	

The following departments/agencies have been consulted

PHARMAC, MBIE, MoH, MFAT, The Treasury, DPMC, Medsafe

Minister's office to complete:

- ☐ Approved
- ☐ Noted
- ☐ Seen
- ☐ See Minister's Notes
- ☐ Declined
- ☐ Needs change
- ☐ Overtaken by Events
- ☐ Withdrawn

Comments

MINISTRY OF HEALTH
MANATŪ HAUORA

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Purchase of COVID-19 vaccines from AstraZeneca Ltd

Date:	3 December 2020	**Priority:**	Urgent
Security classification:	Sensitive	**Tracking number:**	2021-1537

Purpose

To seek approval to terms for the purchase of 3.8 million courses of a potential vaccine against COVID-19 from AstraZeneca Ltd (AstraZeneca). The vaccines are expected to be delivered as early as the second quarter of 2021 (subject to successful development and regulatory approval). Your agreement to the terms is subject to the agreement of the Minister of Finance to provide an indemnity to AstraZeneca.

Executive summary

Background

Our ability to recover from the COVID-19 pandemic and relax public health controls relies on the availability of safe and effective COVID-19 vaccines. The global demand for COVID-19 vaccines continues to be high, and there is heavily constrained capacity to manufacture vaccines.

In response to these challenges the Government:

- approved the Vaccine Strategy [CAB-20-MIN-0229.01] with the objective of ensuring access to safe and effective vaccines for New Zealand and Polynesia.
- established a tagged contingency of up to $600 million [CAB-20-MIN-382] for purposes including advance purchase agreements (APAs) of potential COVID-19 vaccines, and delegated purchase decisions to the Prime Minister, the Minister of Finance, the Minister of Research, Science and Innovation and the Minister of Health (Joint Ministers)
- through Joint Ministers, agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (briefing MBIE 2021–0662 refers).

The 'ideal' vaccine is not yet available to buy. The purchasing strategy aims to pre-purchase a portfolio of potential vaccines through APAs at a stage where the candidates still carry a risk of failure. We have early information about their performance, information about manufacturing processes and plans, and other countries' decisions to enter into APAs.

Money spent on APAs may be lost if the development is unsuccessful, if the candidate is found to be unsuitable for deployment as part of the Government's preferred immunisation strategy, or if the supply is in excess of what is required under that strategy and cannot be on-sold. In the current global context, this is the cost of attempting to secure supply of vaccines that are still being developed.

A 'core portfolio' of COVID-19 vaccines to support achieving population cover can be created before the end of the year

Of the vaccine candidates under development globally, the Vaccine Taskforce has prioritised concluding negotiations with four suppliers by the end of the year: Pfizer Inc. (Pfizer), AstraZeneca Ltd (AstraZeneca), Janssen Pharmaceutica NV (Janssen) and Novavax Inc (Novavax). Securing

these APAs will give us a promising 'core portfolio' that is expected to meet the objective of the Vaccine Strategy of securing access to a safe and effective vaccine. Thus far, Joint Ministers have agreed to purchase two COVID-19 vaccine candidates: 750,000 courses and five million courses of vaccine candidates from Pfizer Inc, and Janssen respectively (MBIE briefings 2021-0996 and 2021-1195 refer). AstraZeneca has offered New Zealand 3.8 million courses of its vaccine candidate for delivery from as early as the second quarter of 2021 for 9(2)(ba)(i), 9(2)(ba)(ii) Accepting the offer would populate the portfolio with a second candidate able to provide broad population coverage. We hope to conclude negotiations with Novavax within the next fortnight. We will also brief you on potentially increasing the volume of vaccines available to New Zealand from Pfizer.

AstraZeneca's offer is time-limited, and it is imperative that the purchase agreement is concluded promptly in order to secure the vaccines for New Zealand from a global allocation.

With a 'core portfolio' secured (including increased vaccines from Pfizer) one or two smaller purchases, including purchases through the COVAX Facility, may be necessary to give the portfolio sufficient diversity to provide a high degree of confidence that it will achieve the Vaccine Strategy's objectives.

Overall, this vaccine appears to meet the purchase framework criteria

The purchase framework considers vaccine performance, availability and access, and contribution to portfolio balance and strategic fit. We have taken advice from Bell Gully, and an independent science advisory panel during the negotiation. PHARMAC has also been involved. Our advice takes into account media reports last week about the trials for the vaccine. The negotiated purchase offer, which is a legally binding full purchase agreement, is attached in Annex One.

We recommend agreeing to the AstraZeneca offer because:

- subject to clinical trials, it could provide broad population cover within the timeframes required to implement the immunisation programme planned for 2021 and 2022.
- AstraZeneca, as part of a global operation, has a proven track record in developing, manufacturing and delivering pharmaceutical products that meets New Zealand's quality standards.
- it is one of the two most purchased vaccines globally, and our own purchase framework analysis supports those decisions.
- early results suggest that this vaccine is equally immunogenic (capable of inducing an immune response) in older and younger population groups. The vaccine may also reduce transmission as it could be effective against asymptomatic infection.

Like other vaccine candidates, its major disadvantage is that it may cause temporary side-effects which may have an impact on the implementation and effectiveness of the immunisation programme, as well as potentially reducing the acceptance of COVID-19 vaccine and routine immunisation programmes.

At around 9(2)(ba)(i), 9(2)(ba)(ii) (consisting of two doses), the purchase price represents a not-for-profit pandemic price 9(2)(ba)(i), 9(2)(ba)(ii) However, the not-for-profit model used globally by the seller transfers some financial risks to the purchaser. We consider these to be manageable. We recommend drawing-down 9(2)(ba)(i), 9(2)(ba)(ii) from the "Minimising the health impacts of COVID-19 – Tagged Operating Contingency" to fund the purchase of the vaccines and to address foreign exchange risk. 9(2)(ba)(i), 9(2)(ba)(ii)

All suppliers of vaccines are requiring purchasers to indemnify them against product liability claims. This reflects the accelerated development of COVID-19 vaccines which prevents the risk from being covered by insurance. 9(2)(ba)(i), 9(2)(ba)(ii) We

are advised that the risks associated with claims in connection with the distribution, administration, and use of the AstraZeneca vaccine which would not be covered by the Accident Compensation Act seem likely to be relatively low, with the Crown able to take certain steps to protect its position as far as possible. 9(2)(ba)(i), 9(2)(ba)(ii), 9(2)(j)

Regulatory approval

Safety and effectiveness will need to be established before COVID-19 vaccines are deployed. We understand that Medsafe has agreed to a rolling submission from AstraZeneca, but the time frame for data to be provided to Medsafe has not been confirmed. We understand AstraZeneca is aware of the need to engage with the Environmental Protection Authority regarding whether their approval is required for the vaccine to be used in New Zealand under the Hazardous Substances and New Organisms Act 1996.

Next steps

Subject to your agreement to the recommendations in this briefing, and the Minister of Finance's agreement to provide an indemnity for AstraZeneca, the Director-General of Health, on behalf of the New Zealand Government, will sign the proposed supply agreement attached at Annex One.

Subject to your agreement to the purchase terms with AstraZeneca, we will work with them and with Ministers' offices to plan communications and publicity opportunities, including an announcement in support of the agreement.

Recommended action

The Ministry of Business, Innovation and Employment and the Ministry of Health recommend that you:

a) **Note** the information in this briefing is subject to confidential disclosure agreements with vaccine developers.

Noted

b) **Note** an unprecedented global health crisis continues and the New Zealand population remains almost totally susceptible to COVID-19 due to our successful elimination strategy.

Noted

c) **Note** the global demand for COVID-19 vaccines continues to be high, and capacity to manufacture successful vaccine candidates is heavily constrained worldwide, and this situation is likely to continue for some time. Advanced economies are pre-purchasing multiple COVID-19 vaccine candidates to mitigate the risk of development failure.

Noted

d) **Note** in May Cabinet approved the COVID-19 Vaccine Strategy [CAB-20-MIN-0229.01] with the objective of ensuring access to a safe and effective vaccine to implement the Government's preferred immunisation strategy at the earliest possible time.

Noted

e) **Note** in August Cabinet established a tagged contingency of up to $600 million [CAB-20-MIN—382] for purposes including the advance purchase arrangements of potential COVID-19 vaccines, Cabinet also delegated purchase decisions to Joint Ministers.

Noted

f) **Note** in September Joint Ministers agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (briefing MBIE 2021 – 0662 refers).

Noted

g) **Note** we have been assessing vaccine candidates prioritised by the Vaccine Taskforce against the purchase framework.

Noted

h) **Note** you have agreed to accept an offer from Pfizer Inc. for the purchase of 750,000 courses of an mRNA vaccine candidate for delivery early next year (briefing MBIE 2021-0996 refers) and to non-binding terms from Janssen Pharmaceutica NV for the purchase of five million courses of a viral vector vaccine for delivery in 2021 and 2022.

Noted

i) **Note** there is an opportunity to purchase 3.8 million courses of AstraZeneca Ltd's vaccine candidate for delivery as early as the second quarter of 2021.

Noted

j) **Note** the negotiations for this purchase opportunity have been carried out with advice from legal and science experts. We have achieved a number of important concessions such as halving the amount at risk as an advance payment, and obtaining the ability to resell or pass on vaccines to the Realm, Polynesia and other Pacific countries.

Noted

k) **Agree** to terms for the purchase of 3.8 million courses of AstraZeneca Ltd's COVID-19 vaccine candidate (the terms are attached in Annex One), at a cost of 9(2)(ba)(i), 9(2)(ba)(ii) (which includes provision of 9(2)(ba)(i), 9(2)(ba)(ii) to address the risk of foreign exchange rate fluctuations). Your agreement is subject to the Minister of Finance's agreement to grant an indemnity to AstraZeneca.

Agree / Disagree

l) **Agree**, if you agree to the recommendation in k), and the Minister of Finance agrees to grant an indemnity to AstraZeneca, the Director-General of Health sign the supply agreement on behalf of the New Zealand Government to give effect to the decision in k).

Agree / Disagree

m) **Agree**, if you agree to the recommendation in k), to draw down 9(2)(ba)(i), 9(2)(ba)(ii) from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' to purchase the AstraZeneca vaccine candidate.

Agree / Disagree

n) **Approve**, if you agree to the recommendation in k), the following changes to appropriations to provide for the decision in recommendation m) above, with a corresponding impact on the operating balance and net core Crown debt:

	$m - increase/(decrease)				
Vote Health **Minister of Health**	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**2024/25 & Outyears**
Non-Departmental Output Expenses: Minimising the Health Impacts of COVID-19	s9(2)(ba)(i), s9(2)(ba)(ii)	-	-	-	-
Total Operating		-	-	-	-

Approve/ Not approve

o) **Authorise** the Minister of Finance and the Minister of Health to transfer any unspent 2020/21 funding in Vote Health agreed under the recommendation n) to the 2021/22 financial year, as required, with no impact on the operating balance and net core Crown debt across the forecast period.

Authorised/ Not authorised

p) **Agree** that the changes to appropriations for 2020/21 above be included in the 2020/21 Supplementary Estimates and that, in the interim, the increase be met from Imprest Supply.

Agree / Disagree

q) **Note** that Treasury officials will seek agreement of the Minister of Finance to the terms of an indemnity for AstraZeneca.

Noted

r) **Note** other negotiations for the advance purchase of COVID-19 vaccines are underway, and we will provide advice on an agreement with Novavax Inc and increased supply of vaccines from Pfizer Inc.

Noted

Rt Hon Jacinda Ardern
Prime Minister
…../…../…..

Hon Grant Robertson
Minister of Finance
…../…../…..

Hon Dr Megan Woods

Minister of Research, Science, Innovation

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

Hon Andrew Little

Minister of Health

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

Maree Roberts

Deputy Director-General,

Ministry of Health

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

Dr Peter Crabtree

GM, Science, Innovation, International, MBIE

01/ 12 / 2020

Background

Global demand for COVID-19 vaccines remains high

1. An unprecedented health crisis continues worldwide, and New Zealand's population remains entirely susceptible to COVID-19 due to our successful elimination strategy.

2. Our ability to recover from the COVID-19 pandemic and relax public health controls relies on the availability of safe and effective COVID-19 vaccines. The global demand for COVID-19 vaccines continues to be high, and capacity to manufacture successful vaccine candidates is heavily constrained worldwide. This is expected to be the case for some time.

Ministers have previously agreed to a COVID-19 vaccine purchasing strategy and a framework to guide purchase decisions

3. In May, Cabinet agreed a purchasing strategy to support acquisition of COVID-19 vaccines [CAB 20-MIN-0382]. A portfolio approach is intended to manage a range of risks and provide safe and effective vaccines to choose from for early deployment as part of New Zealand's immunisation strategy. This improves the chances of acquiring vaccines that can support achieving population cover from COVID-19 in a timely manner. The construction of the portfolio therefore requires the selection of vaccine candidates that ensure diversity across technology platforms, vaccine characteristics, suppliers, and timeframes, and that are suitable for use in the Realm of New Zealand and other Polynesian countries.

4. In August, Cabinet established a tagged contingency of up to $600 million [CAB-20-MIN-382] in order to finance advance purchase agreements (APAs) of potential COVID-19 vaccines and to meet additional early costs for Government's immunisation programme. Cabinet delegated purchase decisions to the Prime Minister, the Minister of Finance, the Minister of Research, Science and Innovation and the Minister of Health (Joint Ministers).

5. Joint Ministers have agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (briefing MBIE 2021 – 0662 refers). The application of the framework criteria is intended to ensure that APAs align with New Zealand's overall objectives for responding to COVID-19 and recognise that our decisions on advance purchasing will be made on the basis of early-stage information.

6. Once concluded, APAs will commit New Zealand to the purchase of vaccines, conditional on successful clinical trials of the vaccine candidate and regulatory approval in New Zealand. Money spent on APAs will be lost if the development is unsuccessful, if the candidate is found to be unsuitable for deployment as part of the Government's preferred immunisation strategy, or if the supply is in excess of what is required under that strategy and cannot be on-sold. In the current global context, this is the cost of attempting to secure supply of vaccines that are still being developed.

7. In effect the cost of COVID-19 vaccines includes the 'insurance premium' of pre-purchasing a portfolio that manages risk and provides sufficient options to implement our preferred immunisation programme. COVID-19 vaccines need to play a different role in New Zealand compared to countries with uncontrolled spread of COVID-19. That is because in the latter, even marginally effective vaccines that are administered to any proportion of their population will likely be an improvement on their status quo. For us, on the other hand, we need to use the most effective vaccines, and aim for broad vaccination uptake, to reach the level of population cover that would support safely reconnecting with the world and moving away from more blunt and costly public health measures.

8. It is still too early to tell which vaccine will be ideal for New Zealand and Polynesian countries. It's also likely we will need a range of vaccines for different people, to achieve the broadest possible uptake. Combined with all the other uncertainties we are trying to manage, this is why we have adopted a portfolio approach and accepted that the actual cost of an effective

vaccination programme will be more than the vaccines that may eventually be used in New Zealand's immunisation programme.

9. As a consequence of their accelerated development, vaccine manufacturers are requiring COVID-19 vaccine APAs to indemnify them against product liability claims. In normal circumstances the risk can be covered by insurance, but this will not be the case for COVID-19 vaccines where self-insurance and risk sharing between the parties is required to secure timely access to vaccines.

10. Decisions to be taken later, including whether to use these vaccines in New Zealand, or whether to offer any vaccines to Polynesia, will depend on their suitability for deployment, either as part of New Zealand's immunisation strategy, or in Polynesia.

11. Discussion with international counterparts and media announcements indicate a number of like-minded countries have reserved large quantities of a number of vaccine candidates through APAs in order to mitigate the risk that vaccine candidates could fail.

A 'core portfolio' of COVID-19 vaccines to support achieving population cover from COVID-19 could be settled before the end of the year

12. The 'ideal' vaccine is not yet available to buy. In order to have high confidence of achieving the objective of acquiring sufficient safe and effective vaccines for timely use in New Zealand and Polynesia, our portfolio requires four vaccine candidates available in quantities to provide broad population cover. From information available now, four candidates represent the point at which we consider the portfolio will have sufficient diversity to manage risks with respect to technology platform, vaccine characteristics, global supply constraints and failure to achieve timely regulatory approval (MBIE briefing 2021-1124 refers).

13. From the vaccine candidates globally under development we have progressed negotiations with eight targeted vaccine suppliers. The COVID-19 Vaccine Strategy Taskforce have prioritised concluding negotiations with four of those suppliers by the end of the year: Pfizer Inc, AstraZeneca Ltd (AstraZeneca), Janssen Pharmaceutica NV (Janssen) and Novavax Inc. (Novavax). Together these APAs will give us a promising 'core portfolio'. The composition of the portfolio aligns with the approach taken by other advanced economies through their APAs.

14. Information about these candidates is broadly promising and we do not have any major concerns from early clinical trial information. The table in Annex Two summarises the population coverage being sought, price and delivery times being negotiated for the four priority vaccine candidate targets.

15. In advancing these four negotiations we have relied on commercial, legal and expert scientific advice. We have assessed these offers against the vaccine purchase framework (see discussion from paragraph 26), and our negotiation priorities. We also received advice and endorsement from portfolio managers of financial portfolios on the overall approach to the construction of our vaccine portfolio.

16. Joint Ministers have agreed to terms to purchase 750,000 courses and five million courses of vaccine candidates from Pfizer and Janssen respectively (MBIE briefings 2021-0996 and 2021-1195 refer). AstraZeneca's offer is outlined below. Negotiations are at an advanced stage with Novavax. We will advise you on terms for that purchase and on an offer for additional vaccines from Pfizer.

17. The AstraZeneca offer is time-limited, and it is imperative that the supply agreement is concluded without delay because New Zealand's vaccine allocation is held temporarily from the global allocation. We are therefore advising you on purchase decisions as each negotiation concludes. There is limited control over the sequence of purchases. As discussed

below, we have signalled our interest in acquiring more AstraZeneca vaccines through the COVAX Facility.

18. It is likely that our vaccine portfolio approach will ensure New Zealand and Polynesia have access to a safe and effective vaccine candidate suitable for use in the immunisation programme. However, additional purchases may be required at a later stage to give the portfolio enough options to create a higher degree of confidence.

The purchase from AstraZeneca could provide sufficient COVID-19 vaccines for broad population cover

19. AstraZeneca has offered New Zealand 3.8 million courses of its vaccine candidate (known as AZD1222) for delivery as early as the second quarter of 2021. This is the amount available to New Zealand at this time. The candidate is a non-replicating viral vector vaccine administered intra-muscularly in two doses at least a month apart.[1] It will cost 9(2)(ba)(i), 9(2)(ba)(ii) which AstraZeneca represents as a not-for-profit global pandemic price. If successfully developed and delivered this vaccine purchase will cost 9(2)(ba)(i), 9(2)(ba)(ii) (which requires a total of 9(2)(ba)(i), 9(2)(ba)(ii)

20. Non-replicating viral vector vaccines are a relatively new technology. The viral vector used in the vaccine candidate has been used previously in a MERS vaccine, and there have been unlicensed vaccines based on the same platform for malaria, HIV, influenza, hepatitis C, tuberculosis, Ebola and others.

21. Similarly to the negotiations with the other three priority vaccine candidate suppliers, negotiations with AstraZeneca have been prioritised because there is high confidence in the ability of the supplier to develop, manufacture and deliver a COVID-19 vaccine to required quality standards.

22. While there are inherent risks to the delivery time of all vaccine candidates, there is a potential to receive a large number of doses of this vaccine before the end of 2021, which would support efforts to prevent and manage the risk of COVID-19 in a timely manner.

23. The Ministry of Health is leading on the COVID-19 Immunisation Programme, which will provide an 'operational blueprint' for rolling out the vaccine once it is available.

24. The terms of AstraZeneca's offer to sell the vaccines to New Zealand are contained in the legally binding supply agreement attached as Annex One. 9(2)(ba)(i), 9(2)(ba)(ii)

We recommend purchasing the AstraZeneca COVID-19 vaccine candidate

25. We believe there is a strong rationale to sign the purchase agreement because:

    - Subject to successful clinical trials, this vaccine will be able to provide broad population cover in a timeframe suitable for the immunisation programme.

[1] The candidate works by carrying DNA into human cells that then produce vaccine antigen (SARS-CoV-2 virus spike protein). The antigen elicits an immune response to the disease.
[2] The sale price is denominated in USD and the vaccine costs 9(2)(ba)(i), 9(2)(ba)(ii) Using today's indicative NZD-USD exchange rate of 0.6595 the estimated cost of each vaccine is [redacted] There is a foreign exchange risk because the price is denominated in USD, and the Treasury have recommended including headroom of [redacted] million to address that risk.

- AstraZeneca, as part of a global operation, has a very strong track record in producing safe and efficacious pharmaceutical products for use globally and in New Zealand. This gives us confidence in their ability to develop, manufacture and deliver a vaccine to prescribed standards.
- We have negotiated terms that we believe are satisfactory, and are in line with global trends for COVID-19 vaccine advance purchase arrangements.
- It is one of the most purchased vaccine candidates. Together, the USA, the UK, Canada, Japan, Australia and the EU have advance purchase arrangements for over 430 million courses of this vaccine candidate[3]. Many of these countries have used similar purchase frameworks to ours, using their experts to interrogate the early science results, trial designs and manufacturing programmes. It is also in the COVAX Facility portfolio.
- The candidate is likely to be available to be delivered earlier than the Janssen vaccine (the previously purchased broad population cover vaccine). At this stage we are able to secure 3.8 million courses, which would provide broad, but not full, population cover for New Zealand and the Realm. However, it may be possible to secure additional amounts through the COVAX Facility, should this be desirable for New Zealand's immunisation strategy.
- Older populations tend to have dampened immune responses to vaccines. Early results suggest that this vaccine is equally immunogenic in older and younger population groups. The vaccine may also reduce transmission as it could be effective against asymptomatic infection. Recent research indicates that almost half of all people infected with COVID-19 are asymptomatic.
- While early results show some promise, as with other candidates, trial data suggest there are temporary side-effects from the vaccination, which may impact on the implementation of an immunisation programme. However, side effects appear to be lower in older people than other age groups vaccinated.

Overall, this vaccine appears to meet the purchase framework criteria

26. The vaccine purchase framework is outlined in Annex Three. It considers expected vaccine performance, expected availability and access, and contribution to portfolio balance and strategic approach. Vaccine performance considers criteria such as safety profile, effectiveness and ease of distribution across the population as a whole and to particular population groups. Availability and access considers factors such as confidence in production, contractual terms and geopolitical dynamics and international risks. In advance of full vaccine development and regulatory approval and in the absence of final data, the framework uses proxies to help inform choices.

27. We took a multi-agency approach in negotiations to strengthen the level of interrogation. We have taken advice from Bell Gully, as well as from an independent scientific and clinical review panel, to help inform our analysis of the offer and information about the vaccine candidate, the developer and the supplier. Overall, we consider that the criteria in the framework have been met to a satisfactory level. That analysis is discussed below, with further detail attached as Annex Four.

[3] The USA has purchased 150 million courses, the UK has purchased 50 million courses, Canada has purchased 10 million courses, Japan has purchased 60 million courses, Australia has purchased 16 million courses and the EU has purchased 150 million courses. The COVAX Facility has secured 150 million courses.

Application of vaccine purchase framework criteria

	Criteria	Importance	Assessment of criteria	Level of satisfaction of criteria
Performance	**Safety profile and effectiveness**	Critical	As confident as we can be from early information	✓ ✓ ✓ *
	Ease of distribution	High	There may be some issues with vaccine acceptance. Distribution is generally in line with norms	✓ ✓ ✓
	APAs with other countries	High	Large number of APAs concluded	✓ ✓ ✓
Accessibility	**Production**	Critical	Confidence in planned production	✓ ✓ ✓
	Contracting	High	Satisfactory contractual terms negotiated	✓ ✓
	International risk	High	International risk is low	✓ ✓✓
	Comparable price offered to others	High	International price achieved	✓ ✓ ✓
Portfolio	**Portfolio fit**	Critical	Good fit with portfolio strategy	✓ ✓ ✓

Key: ✓✓✓ high satisfaction of criteria; ✓✓moderate satisfaction of criteria; ✓ satisfaction of criteria; • criteria not met.

* From limited data. It will be essential to see data from phase III human trials for this candidate before drawing conclusions about its safety, immunogenicity and efficacy.

The candidate shows some promise in terms of performance

28. AstraZeneca and the University of Oxford released information about Phase III clinical trial results on 23 November. The main regimen, consisting of two full doses given at least a month apart, appeared to be 62 percent effective. But in a smaller group of participants who (due to a dosing error) received a half dose followed by a full second dose, the vaccine appeared to be 90 percent effective. The half-dose/full-dose regimen looks promising, but there have been too few cases of COVID-19 in the trial to make reliable judgements about the statistical significance of the results at this stage. We also understand that the participants in the sub-group that received the half-dose/full-dose regimen were all aged under 55, which may have contributed to the high efficacy observed in that group. Further clinical trial results will validate both regimens in a larger number of people, which will provide more reliable information about the efficacy of the two regimens. Care must be taken with all interim results, as they are based on relatively small numbers and ongoing trial data will provide greater understanding of vaccine performance. Commentary from the science review panel provided on 25 November 2020 is attached as Annex Five.

29. We will continue to monitor new information about safety and efficacy as clinical trial data becomes available, and we note that more information will be available at the time decisions are made whether to use the vaccine. Specifically, in relation to two criteria which contribute to vaccine performance this candidate shows some promise:

    - Safety – Previous (unlicensed) vaccines based on this platform are considered by the developer to have a good safety profile in humans. Adenovirus-vectored vaccines have also been researched and used extensively for decades with good safety profiles. Reactogenicity (common adverse reactions such as headaches and fatigue) has been

observed in early trials of all key vaccine candidates, which may have an impact on the implementation of the immunisation programme, as well as potentially reducing the acceptance of COVID-19 vaccines and routine immunisation programmes. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

- As with other COVID-19 candidate vaccines, there is the potential for safety issues including disease enhancement after vaccination. Additional data about safety will be available from human trials at the time a decision is taken in New Zealand on whether or not to use a vaccine. It may also be possible at that stage to mitigate perception risks through communications planned as part of the immunisation programme.

- Effectiveness – The interim phase III data builds on earlier phase I/II peer-reviewed trial results, which have shown that the vaccine induces strong antibody and white blood cell immune responses across all age groups, including older adults. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

- The vector in this vaccine is based on a chimpanzee virus. This means that pre-existing immunity (and theoretical risk of dampening response to the vaccine) in humans is likely to be lower for this vaccine compared to COVID-19 vaccines based on a human viral vector. However, it is not yet known if memory immune responses will develop against the viral vector post-vaccination, and whether this will affect later boosters.

Recent media statements about the efficacy of vaccine candidates provide little new information

30. In the last two weeks Pfizer, Moderna and AstraZeneca have made media statements about the efficacy of their vaccine candidates. We should be cautious about drawing conclusions from these statements about the suitability of their vaccines for our preferred portfolio because:

    - the statements are media messages rather than clinical data about the safety and efficacy of the candidates and there is little that can be concluded other than there appears to be some efficacy
    - the claims of efficacy are not directly comparable between the candidates
    - regulators will need to view data to assess efficacy and safety, including to enable comparisons to be made between the candidates.

31. There has been some media comment about manufacturing and testing errors that resulted in the half-dose/full-dose regimen being given to some participants. These types of errors are not unusual in clinical trials of pharmaceutical products, with risks expected to increase for products being manufactured and tested at speed. AstraZeneca's situation is not likely to be an isolated case, and we have observed that other suppliers, such as Pfizer, are signalling delays in the availability of information about their manufacture and quality control processes.

32. AstraZeneca consider that there is strong merit in continuing to further investigate the half-dose/full-dose regimen. We are advised that they are evaluating the data and will work with regulators on the best approach for further evaluation, however we do not know the timing of the additional trials, or whether the trials and the regulatory approval of the second regimen

would be completed before our vaccines are delivered. Existing clinical trials will continue as planned, and AstraZeneca is preparing for regulatory submissions based on these trials.

Deployment requirements are within general expectations for COVID-19 vaccines

33. The vaccine is distributed using standard 2-8 degree Celsius cold chain methods. You have agreed to draw down $66.3 million from the tagged contingency to urgently purchase critical resources for the immunisation programme, including resources to support cold chain capacity around New Zealand, of the type needed to deploy this vaccine candidate (briefing MoH 20201744 refers).

The AstraZeneca candidate is one of the two most purchased vaccine candidates in our target group

34. An important proxy indicator of vaccine performance is the extent to which APAs have been concluded with other countries who have greater resources to vet candidates and use the same purchase frameworks to ours. AstraZeneca has concluded arrangements with the USA, the UK, Canada, Japan, Australia, the EU and COVAX Facility for the sale of over 580 million courses of its vaccine candidate

If the clinical trials are successful, there is strong confidence that AstraZeneca will be able to supply the vaccine to New Zealand

35. AstraZeneca's global operation is a highly reputable global biopharmaceutical enterprise. While AstraZeneca has not supplied a vaccine in New Zealand, it is a major supplier of pharmaceuticals in New Zealand, including injectable products. There is confidence in the parent company to manufacture and deliver a product that meets New Zealand's quality standards. It does not appear that the supplier is selling above their capacity to deliver.

36. AstraZeneca has indicated that New Zealand's vaccines are likely to be manufactured in the United States. The United States has purchased 150 million courses of the AstraZeneca candidate. 6(a) [redacted] Notwithstanding upcoming regime change, the White House in October published an Executive Order mandating that COVID-19 medicines and medical supplies for United States consumption should be purchased from US-owned companies, and similar measures could be put in place to control the movement of COVID-19 vaccines into and out of the United States. 6(a) [redacted] Astra Zeneca's geographically diversified supply chains may also provide a mitigation.

Delivery schedules are not certain, deliveries may be delayed and there is no guarantee of a vaccine

37. AstraZeneca has confirmed its expectation that New Zealand will receive vaccines from the second quarter of 2021. However, the terms do not create fixed delivery obligations. This is common to all candidates because vaccines are not yet approved for use in New Zealand, trials are ongoing, and manufacturing scale-up has not been completed. Factors that will have an impact on the eventual delivery schedule include when the supplier can provide data to Medsafe for assessment, including further trialling data for the half-dose/full-dose regimen.

The vaccine is reasonably priced and is not expected to have significant additional administration costs

38. The supplier has made a commitment to making their vaccine candidate available globally on a not-for-profit basis during the emergency pandemic response period. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

9(2)(ba)(i), 9(2)(ba)(ii) AstraZeneca will probably transition to commercial pricing at the end of the emergency pandemic period.

39. Distribution and deployment costs are generally likely to be within the normal range for COVID-19 vaccines. However, recent information from interim phase III clinical trial data suggests that the best immunological response may be achieved if the first dose contains half the product of the second dose. It is not yet know if the dosing regimen would follow this format, but a regimen with this type of variation could increase administrative complexity.

The vaccine could play an important role in the portfolio to provide broad population cover and be effective for older people

40. Older populations tend to have dampened immune responses to vaccines. Early results suggest that this vaccine is equally immunogenic in older and younger population groups. Older people are also at higher risk of severe outcomes from the disease and may benefit the most from access to a vaccine that prevents disease or reduces the severity of the illness. This vaccine also appears to be less reactogenic in older people than younger people

41. Similar to Janssen's vaccine, the AstraZeneca vaccine could offer broad population cover and is based on non-replicating viral vector technology. This is one of the three platform types we expect the 'core portfolio' to include.

42. Broad population coverage purchases provide significant benefit to the portfolio as they reduce the need for multiple candidates to succeed before we are able to achieve-wide population cover. On the other hand, the vaccines that could offer broad coverage all have different drawbacks that could prevent their widespread use. This is why we are building a portfolio of vaccines: to maximise options for the immunisation programme, and increase our chances of having safe and effective vaccines for population-wide deployment. This reflects the approach taken by other countries using similar purchase frameworks to ours, and a number have purchase agreements for both the Janssen and AstraZeneca viral vector candidates.

43. Not purchasing the AstraZeneca candidate would have the following implications for the portfolio:

    - Assuming that additional vaccines are purchased from Pfizer and an agreement is concluded with Novavax, we may need to consider purchasing a different vaccine candidate to form the core portfolio of four candidates with wide coverage. There is only one viable alternative at present, based on negotiations already underway. That vaccine candidate has not yet reported results from human trials, and early issues have been raised that could affect public trust and confidence in it. These issues may be resolvable (or their impact may have been over-estimated), but we would be unlikely to recommend purchasing that candidate until we have more information.
    - If an alternative to the AstraZeneca vaccine candidate was not pursued, the portfolio would only have two (or three if sufficient Pfizer vaccines are purchased) vaccine candidates that provide broad population cover. It may still have one candidate from each of the three main platforms we are targeting, but there would be reduced options for the immunisation programme when deciding what vaccines to deploy and when.

The proposed terms permit passing on vaccines to Pacific countries with AstraZeneca's consent

44. In August the previous Minister of Foreign Affairs agreed in principle that Official Development Assistance (ODA) could be used to reimburse the cost of vaccines passed on to Polynesian countries. The Minister of Foreign Affairs is expected to bring a paper to Cabinet in December 2020 seeking approval for a funding envelope from reprioritised ODA to give effect to this decision.

45. AstraZeneca can foresee no specific issues which would impact distribution of this vaccine to the Pacific at this stage, other than the need for refrigeration (which is less challenging than

the frozen distribution required for some other candidates). 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

46. If a decision is made to use this vaccine for broad population cover in New Zealand we cannot be certain there will be sufficient quantity to offer it to wider Polynesia beyond the Realm. Australia has stated that it intends to donate AstraZeneca vaccines that are in excess of its domestic needs.

Opportunities for local manufacture of vaccines was sought as a means of mitigating supply risks

47. The supplier has ruled out permitting the manufacture of its vaccines in New Zealand. They indicated that their resources to extend their manufacturing programme were stretched and the quantities that could be produced in New Zealand did not warrant redistributing those resources. They have indicated that New Zealand's vaccines will likely be manufactured in the United States.

New Zealand is pursuing the opportunity to purchase more of this vaccine through the COVAX Facility

48. Joint Ministers agreed to purchase COVID-19 vaccines through COVAX for up to 50 percent of New Zealand's and the Realm's adult population and to join via its Optional Purchase Arrangement (briefing MBIE-2021-0858 refers). Under this arrangement, we will receive 'purchase opportunities' (an option to purchase) for vaccine candidates as they are added to the Facility's own portfolio.

49. We have expressed interest in purchasing the first three candidates offered through the Facility: Pfizer, AstraZeneca, and Sanofi/GSK. The Pfizer and AstraZeneca opportunities provide us with a potential pathway to top up the portfolio, while the Sanofi opportunity provides us with a way of accessing a promising vaccine that we have not been able to secure independently.

50. The COVAX Facility is still negotiating with vaccine developers, there are still a range of details (such as pricing and volumes) to be finalised before we are offered final purchase options on these three candidates. Initial documentation from the Facility implies that this will likely be around December 2020 – February 2021.

Commercial considerations

51. We have taken legal and commercial advice from Bell Gully and others during the negotiation of terms with AstraZeneca. PHARMAC has also been involved in the negotiations. We consider that a good outcome has been achieved. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] Mutually acceptable outcomes have been achieved where New Zealand had to make concessions.

52. The terms in the proposed supply agreement are in line with the negotiating priorities agreed with the Vaccine Taskforce, and we understand they are in line with commercial expectations, 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] An outline of how the terms compare to negotiating priorities is included in Annex Six.

53. In summary:

Price	• The price is agreed, it is denominated in US dollars so there is some foreign exchange risk. The Treasury has advised that it is preferable for New Zealand to manage the exchange risk.

	• 9(2)(ba)(i), 9(2)(ba)(ii) This reflects the not-for-profit pandemic price approach taken which shares development risk between the parties.
Delivery, supply and logistics	• The number of vaccines secured is the maximum available at this stage, though more can be sought through the COVAX Facility. • The commitment to supply is adjusted to take into account the uncertainty in vaccine development and requirements for regulatory approval. • The supplier will use reasonable efforts to seek regulatory approval and to supply the vaccine.
Additional courses and resale	• Vaccine courses in addition to the 3.8 million provided will be subject to a subsequent agreement. • There is an ability to pass on vaccines to Realm and Pacific countries.
Logistical support	• None needed from supplier.
Commercial considerations	• The agreement will be governed by New Zealand law. • 9(2)(ba)(i), 9(2)(ba)(ii) • The parties have concluded a confidential disclosure agreement.

9(2)(ba)(i), 9(2)(ba)(ii)

54. All COVID-19 vaccine suppliers are requiring purchasers to provide them with indemnities to protect them against a range of risks. In normal circumstances many of these risks can be covered by insurance, but in the case of COVID-19 vaccines pharmaceutical companies have told us that insurance is unavailable or prohibitively expensive. A robust regulatory approval process is an important mitigation of the risk to the Crown of providing the indemnities.

55. 9(2)(ba)(i), 9(2)(ba)(ii) We expect this is because:

- As with all COVID-19 vaccine development, AstraZeneca is developing the vaccine in accelerated clinical trials that are less likely than non-accelerated trials to detect uncommon adverse effects or possible contraindications. COVID-19 vaccine trials are expected to be shorter and have fewer trial subjects than ordinary pharmaceutical development which will reduce the known safety profile of the vaccine.
- 9(2)(ba)(i), 9(2)(ba)(ii)
- 9(2)(ba)(i), 9(2)(ba)(ii)

9(2)(ba)(i), 9(2)(ba)(ii)

9(2)(ba)(i), 9(2)(ba)(ii)

[redacted]

59. As for the Pfizer indemnity, Bell Gully has advised that the risks associated with claims in connection with the distribution, administration, and use of the AstraZeneca vaccine which would not be covered by the Accident Compensation Act seem likely to be relatively low, with the Crown able to take certain steps to protect its position as far as possible.

9(2)(ba)(i), 9(2)(ba)(ii)

[redacted]

9(2)(ba)(i), 9(2)(ba)(ii)

64. We will provide a business case to the Treasury on the indemnity provision negotiated. The Minister of Finance can give an indemnity under section 65ZD of the Public Finance Act 1989 (PFA) if it appears to the Minister to be necessary or expedient in the public interest to do so. On the basis of the business case, the Treasury will advise the Minister of Finance on whether the indemnity may be considered to meet the public interest test in the PFA. Your agreement to the terms of the supply agreement will be subject to the Minister of Finance's agreement to grant the indemnity.

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

65. If you agree to purchase AstraZeneca's vaccine candidate, a draw-down of 9(2)(ba)(i), 9(2)(ba)(ii) from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' will be required to fund the purchase price for 3.8 million vaccines and headroom to address foreign exchange risks. A draw-down is recommended at this stage because, while the final payments for the purchase will be contingent on the successful development of the vaccine, the execution of the supply agreement indicates a clear intention to purchase the vaccines.

66. The draw-down would enable the following payments to be made:

Payment	Timing	Cost (NZ$)
Initial payment	9(2)(ba)(i), 9(2)(ba)(ii)	9(2)(ba)(i), 9(2)(ba)(ii)
Delivery payments	From second quarter of 2021	
Total		

9(2)(ba)(i), 9(2)(ba)(ii)

67. We are seeking agreement to appropriate the total amount of funding into the current financial year because the delivery and payment schedules are uncertain and are expected to fall in the cusp between the current financial year and the next financial year. This will minimise the risk of funding not being available if all the payments are required to be made in the current financial year. Also, to address the eventuality that payments will be required in the 2021/22 year, we recommend that you authorise the Minister of Finance and the Minister of Health to transfer any unspent 2020/21 funding to the 2021/22 financial year.

Regulatory approvals will be a separate process

68. No COVID-19 vaccine can be used as part of an immunisation programme within New Zealand until it has received regulatory approval from Medsafe (and the Environmental Protection Authority where relevant). Medsafe have agreed to a rolling submission from AstraZeneca, to make the best use of information as it becomes available. The timeframe for data to be sent to Medsafe have not been confirmed but AstraZeneca suggest a full set of data will not be available until next year. The time required to achieve regulatory approval is to a large extent dependent on the timeliness and quality of the information provided by suppliers to regulators.

69. Medsafe is actively considering options for expediting the approvals process in order to evaluate a number of concurrent COVID-19 applications, while ensuring that vaccines meet acceptable standards for efficacy, safety and quality. The timeliness and quality of the information provided by suppliers to Medsafe can influence the length of the process for regulatory approval.

70. This candidate may be subject to the Hazardous Substances and New Organisms Act 1996. We understand the supplier is aware of their need to engage with the Environmental Protection Authority.

Communications and publicity

71. There is strong public interest in the efforts of pharmaceutical companies to develop effective and timely COVID-19 vaccines, and also in which countries would likely have access to vaccines once they have been developed and approved for use.

72. Subject to your agreement to execute the supply agreement and the Minister of Finance's agreement to provide an indemnity, we will work with AstraZeneca and with Ministers' offices to discuss communications and publicity opportunities. You may wish to consider aligning media statements for this purchase, and potentially others, with the planned 'Unstoppable Summer' communications campaign scheduled for the week of 14 December.

73. We have provided your offices with questions and answers for use to respond to enquiries, particularly in relation to recent media reports on the AstraZeneca interim trial results.

Next steps

74. Subject to your agreement to the supply agreement, and the Minister of Finance's agreement to provide an indemnity to AstraZeneca, the Director-General of Health will execute the supply agreement on behalf of New Zealand.

75. The advance payment will be made within 30 days of the conclusion of the supply agreement.

76. We will report to you over the next few weeks on the outcomes of the negotiation with Novavax and Pfizer.

Annexes

Annex One: Proposed AstraZeneca supply agreement.

Annex Two: Priority vaccine candidates and contracted delivery schedules.

Annex Three: Summary of vaccine purchase framework.

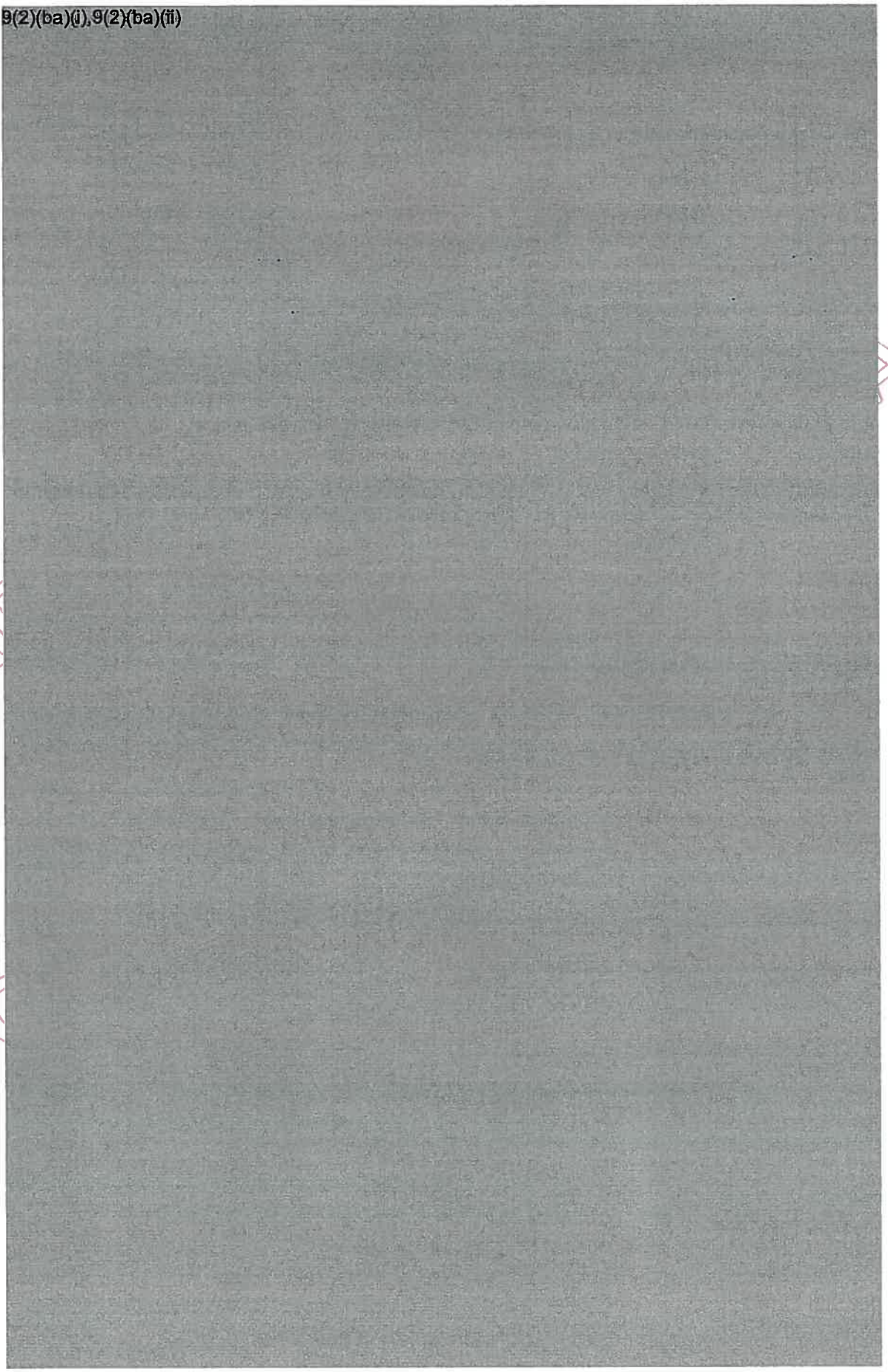
Annex Four: Summary of vaccine purchase framework analysis.

Annex Five: Science review panel commentary.

Annex Six: Summary of comparison of supply terms to negotiation priorities.

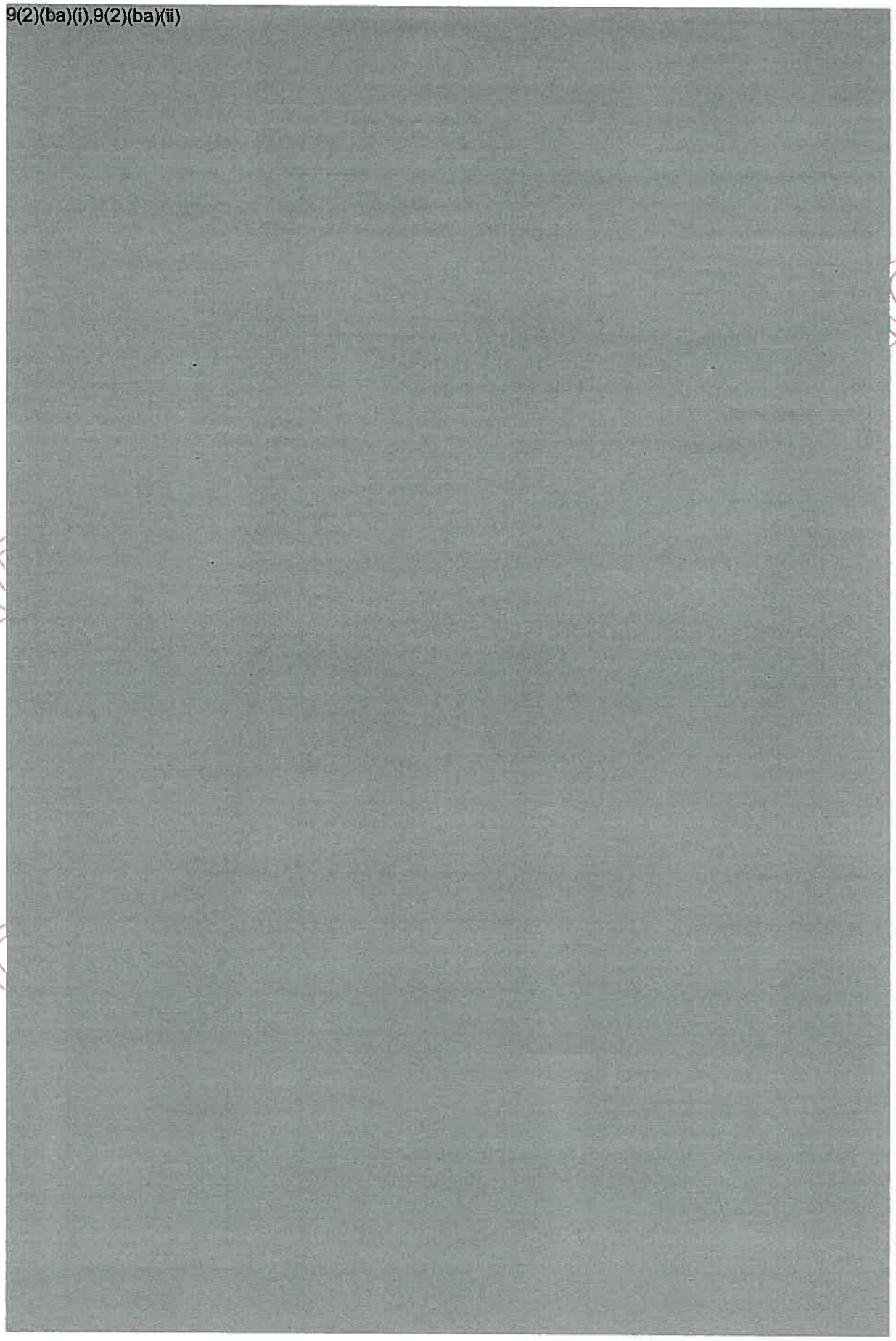
Annex One: Proposed AstraZeneca supply agreement

9(2)(ba)(i), 9(2)(ba)(ii)



Annex Two: Priority vaccine candidates and contracted delivery schedules

9(2)(ba)(i),9(2)(ba)(ii)



Annex Three: Vaccine purchase decision making framework

Ideal set of information for decision making:

1. Vaccine performance	Importance
• Safety profile	CRITICAL
• Effectiveness	CRITICAL
• Ease of distribution across population as a whole or for particular population/ age groups especially Māori	HIGH
• Immunity type: sterilising vs immunity from disease	MED
2. Availability and access	
• Production o Confidence in company (e.g. historic performance) o Reliability of supply chains for raw materials o Capacity (incl. domestic manufacturing and flexibility) o Licensing arrangements o Delivery schedules	CRITICAL
• Price	HIGH
• Contracting o Type of purchasing agreement (e.g. future buy options) o Type of partnership incl. with other countries o Options to manufacture	HIGH
• 6(a) [redacted]	
• COVAX commitments	

What we can assess in absence of full information from clinical trials:

1. Vaccine performance	Importance
• Available data on safety and effectiveness (likely to be limited to preliminary or final results from Phases I/II) [Note: We are highly unlikely to enter into an APA with no indication of safety and effectiveness]	VERY HIGH
• Safety and effectiveness projections of international experts	VERY HIGH
• Existing APAs by like-minded countries	VERY HIGH
• Track record and reputation of the vaccine developer and key scientists (including signals from regulators and CEPI)	HIGH
2. Availability and access	

• Route to manufacture (arrangements in place; funding; CEPI support)	VERY HIGH
• Track record, reputation and reliability of manufacturer	VERY HIGH
• Existing APAs by like-minded countries	VERY HIGH
• International risk assessment	HIGH
• Price offered to other countries	VERY HIGH

3. Contribution to portfolio balance and strategic approach

To manage risks, the portfolio needs diversity across technology platforms, suppliers, timeframes, and equitable population coverage (including the Pacific). This will become more important over time as the portfolio builds.

Annex Four: Summary of vaccine purchase framework analysis

Annex Five: Science Review Panel Commentary

COVID-19 Vaccine Candidate Science Review Panel Commentary

AstraZeneca COVID-19 candidate vaccine

25th November 2020

AstraZeneca presented their candidate viral vector vaccine to the Science Review Panel on 1st October 2020. There are currently no licenced vaccines using this non-replicating viral vector (the ChAdOx1 simian adenovirus-based vector) technology.

Data presented by AstraZeneca from phase 1/2 trials suggest that this candidate is immunogenic with neutralising antibody at a level similar to that in convalescent sera (sera from individuals who have recovered from COVID-19 disease) in participants after 2 doses. Neutralising antibody titres were broadly similar in those over 70 years and those in younger age groups after 2 doses of vaccine. These phase 1/2 data also show this vaccine is reactogenic with more than 50% of participants experiencing each of fatigue, headache, malaise and muscle aches. In keeping with experience for other vaccines, it is less reactogenic in older adults than in younger age-groups. Two serious adverse neurological events (classed as unlikely to be vaccine-related by the trial's Data and Safety Monitoring Board) have been recorded in human trials with this vaccine. Additionally, the developer has not specified whether the produced corona-virus spike antigen is in the pre-fusion conformation (considered to have less potential for generating enhanced disease on re-exposure than post-fusion form).

A number of phase 3 clinical trials are in progress for this vaccine in the UK, USA, Brazil, India and Russia. Trials will mainly include healthy individuals with some elderly participants. In particular, the phase 3 trial in the UK includes 1000 participants aged over 70-years and also children over the age of 5 years. Participants with unstable/severe co-morbid conditions, immunosuppression (except for 50 HIV-infected individuals) and pregnancy are excluded. AstraZeneca has stated that the collection of safety data in phase 3 trials will be continued to completion (12-24 months, depending on study) even if efficacy endpoints are achieved early.

On 23 November 2020, interim results from the Phase 3 clinical trial (UK, Brazil and South Africa) were announced via a press release. These data indicated a vaccine efficacy of 70.4%, based on 131 cases of COVID-19 over 2 different dosing regimens (both received 2-doses at least one month apart, but one arm received a halved first dose). The half-dose followed by full-dose regimen had higher efficacy (90%) than the two full-doses regimen (62%), although the precision of these point estimates is unclear, so they may not be statistically distinguishable. The reason for differences in reported effectiveness of the two different dosing regimens is unclear, although there may be plausible immunological reasons. Regardless, it is critical to first review the detailed analysis of the completed study with greater participant numbers in order to see whether this difference is confirmed. Detailed results of the Phase 3 study are also needed to determine if efficacy varies by important sub-groups (e.g. older age), but importantly there were no COVID-19 cases who were hospitalised or otherwise classified as severe in vaccine recipients. Additionally, and unlike some other COVID-19 candidate vaccines, efficacy against asymptomatic infection is being assessed, with early data suggesting lower rates of asymptomatic infection in vaccines.

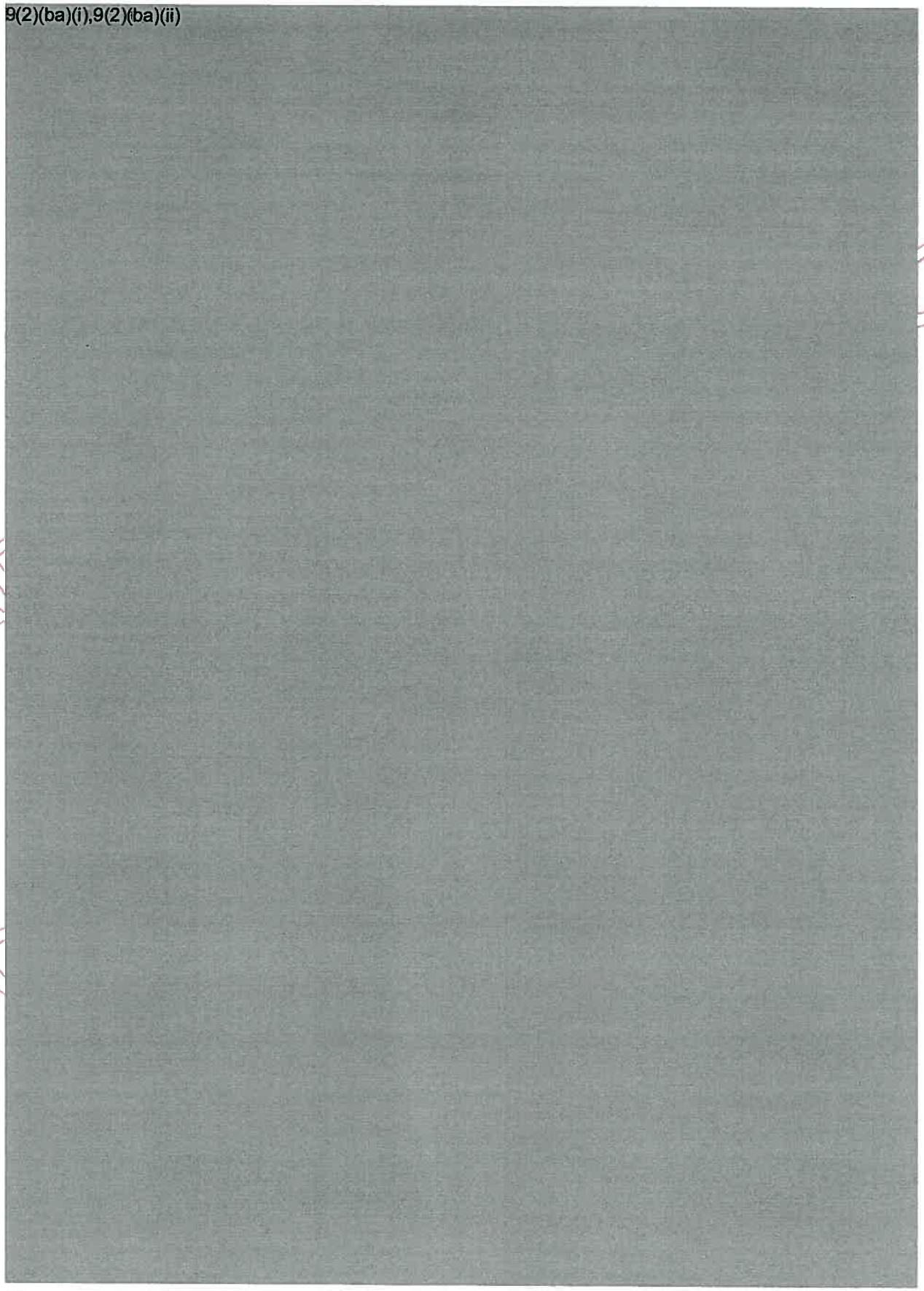
This vaccine is being tested as a 2-dose vaccine regimen given one month apart. It will be presented in multidose vials (up to 10 doses per vial), to be distributed in New Zealand at 2-8°C, which is in line with the NZ standard cold chain for vaccine distribution. Currently, the vial should be used within 4 hours of opening (work is ongoing to assess if longer is possible). While there will be some data for children over the age of 5

years from the UK phase 3 trial, we do not yet know if applications for initial licensure will include children. Although data from non-human primates suggested that viral replication may still occur in the upper respiratory tract in vaccinated individuals, the developer states that early phase 3 trial data suggest that the vaccine may lead to a reduction in transmission as well as disease. As for initial use of all available vaccines, high-risk groups and frontline workers are likely to be targeted first. By the time coverage across the whole population is being contemplated, more data should be available to inform best use in other population groups. If an initial half-dose proves to be important, there will be logistical issues in ensuring that this is received first, requiring robust procedures to ensure it.

AstraZeneca are aiming to produce 2 billion doses of vaccine. This will require substantial supply chain and manufacturing planning which is in progress. The developers hope to complete their dossier for EMA by the end of 2020, which would mean potential approval in January 2021. Expected delivery dates to New Zealand are still being investigated, but developers suggest Q3 of 2021 (or possibly small amounts earlier) may be viable. New Zealand's supply is currently planned to be produced in the USA rather than Australia which may present issues for supply. Cold chain requirements will be very important in the Pacific. AstraZeneca can foresee no specific issues which would impact distribution of this vaccine to Pacific nations at this stage, other than standard (2-8°C) cold chain requirements, which are already in place.

Annex Six: Summary of comparison of supply terms to negotiation priorities

9(2)(ba)(i),9(2)(ba)(ii)



Application of vaccine purchase decision making framework to the Supply Agreement from AstraZeneca and comment from independent experts

Purpose

This document captures information from negotiations, publicly available sources, advice from experts, and confidential information from trusted sources to apply the vaccine purchase framework to the draft binding terms being negotiated with AstraZeneca. Meeting the criteria in the framework informs the decision to enter an agreement with the supplier to purchase their vaccine candidate. As well as being one of the priority vaccine candidates, the framework criteria are vaccine performance, availability and access, and contribution to portfolio balance.

Process

Vaccine candidates have been prioritised and AstraZeneca's vaccine candidate is ranked within the top five target vaccines for an APA (Advance Purchase Agreement). It has also been judged to be a suitable component in the construction of a 'core portfolio' of vaccine candidates for New Zealand. APA negotiations have concluded.

Overall assessment

We consider that the criteria in the purchase framework have been met:

- Performance: This is one of the two most purchased vaccine candidates in the target group. The vaccine technology has been used before and interim Phase III and Phase I/II data show some promise. Early results suggest it has a higher potential to protect older populations than some other candidates, and may reduce transmission via a reduction in asymptomatic infection. Like other candidates, the vaccine is reactogenic (common adverse effects such as fatigue or headaches).
- Availability and access: There is confidence in the company and its ability to fulfil delivery commitments. AstraZeneca, as part of a global operation, has a very strong track record in producing safe and efficacious pharmaceutical products for use globally and in New Zealand. This gives us confidence in their ability to develop, manufacture and deliver a vaccine to prescribed standards. The negotiated terms are in line with global trends for COVID-19 vaccine advance purchase arrangements, except that the supplier has sought broader indemnity than others. The price is settled and is represented as a global non-profit pandemic price. International risk is assessed as low, though there is some risk of sovereign hoarding. The development is CEPI funded and supply has been secured by the COVAX Facility.

- Contribution to portfolio balance and strategic approach: The candidate is likely to be available to be deployed across the population earlier than the Janssen vaccine (the previously purchased broad population cover vaccine). At this stage we are able to secure 3.8 million courses, which would provide broad, but not full, population cover for New Zealand and the Realm. However, it may be possible to secure additional amounts through the COVAX Facility.

Key to achievement of framework criteria:

- ✓✓✓ Criteria achieved with confidence, based on current information
- ✓✓ Based on the available information, nothing to indicate that criteria will not be met
- ✓ Criteria could be achieved, but there are issues to be resolved
- × Criteria is not achieved, or will not be achieved
- ◆ No indicators available at the time decisions are made

Supplier – ASTRAZENECA LTD (AstraZeneca)			Vaccine Candidate: AZD1222
Platform and description			Non-replicating viral vector vaccine[1].
	Importance	Meet framework criteria	
Priority candidate groups; A, B, C Confidence in priority ranking	Should be in Group A	Group A	***The candidate is ranked highly within priority group A*** Agreement is with local subsidiary of AstraZeneca plc/AB, a British-Swedish multinational with headquarters in the United Kingdom and Sweden. AstraZeneca, as part of a group, is a highly reputable global biopharmaceutical firm. AstraZeneca Ltd is a major pharmaceutical supplier in New Zealand, but has not supplied a vaccine in New Zealand. If successful, is expected to be delivered within the timeframes required to implement the immunisation programme planned for 2021 and 2022.

[1] Based on an existing simian recombinant adenovirus vaccine vector (ChAdOx1). The antigen is produced in the vaccine recipient's cells.

			There is high confidence in the priority ranking, with a caveat around experience with vaccines in New Zealand. The supplier has experience in respiratory diseases, but did not have previous vaccine experience. The supplier has no existing expertise in meeting New Zealand regulatory requirements for vaccines.
Vaccine performance			*What we can assess in absence of full information from trials*
Track record and reputation of the vaccine develop and key scientists (including signals from CEPI and regulators)	High	Good track record and reputation of research capability	The vaccine developers, University of Oxford and Vaccitech Limited, have experience in developing therapeutics and vaccines (for infectious diseases and cancer, such as hepatitis B, HPV and prostate cancer). AstraZeneca is CEPI funded[2].
APAs concluded with other countries	Very high	Large number of APAs concluded globally	***Along with the Janssen candidate, the most vaccine courses secured by APAs*** The following is a list of APAs concluded with other countries, and the number of courses ordered: United States 150 million[3] United Kingdom 50 million[4], Japan 60 million[5], EU 150 million[6], Australia 16 million[7], Canada 10 million[8]. Also Brazil for 50 million, and CEPI for 150 million. Comparator countries have used similar frameworks to ours, using their experts to interrogate the early science results, trial designs and manufacturing programs. The 'top list' of countries for similar safety and efficacy requirements are:

[2] https://www.pharmaceutical-technology.com/news/astrazeneca-vaccine-manufacturing/
[3] https://www.reuters.com/article/us-health-coronavirus-astrazeneca-idUSKBN22X0J9
[4] https://www.reuters.com/article/us-health-coronavirus-britain-astrazenec-idUKKBN27K2GQ?taid=5fa32a3ca9d96800015ce9e9&utm_campaign=trueAnthem:+Trending+Content&utm_medium=trueAnthem&utm_source=twitter
[5] Tokyo FM 13 August).
[6] With option for 50 million more. https://ec.europa.eu/commission/presscorner/detail/en/ip_20_1438
[7] https://www.reuters.com/article/us-health-coronavirus-australia/australia-to-receive-first-batch-of-astrazeneca-covid-19-vaccine-in-january-2021-pm-to-say-idUSKBN25X0HU
[8] https://www.astrazeneca.ca/en/media/press-releases/2020/astrazeneca-and-government-of-canada-announce-agreement-to--supp.html#!.

			• Australia, Europe (centralised process), MHRA (United Kingdom), FDA (United States), Canada, SwissMedic. Singapore is also comparable in terms of risk/benefit assessment. Supplier says committed to supply well in excess of two billion doses which includes providing to United Kingdom, United States, GAVI, South Korea, Russia, Middle East, Balkans, Sweden, Japan, Brazil, Mexico and China, among others.
Clinical trials		Progressed to Phase III	***Clinical trials have progressed to Phase III*** Multiple Phase I/II trials[9] • Phase I/II participant-blinded, multi-centre, randomised controlled trial in 1077 healthy volunteers in the United Kingdom[10]. o Subjects 18 to 55 years, including those with no prior history of symptoms or serological evidence of COVID-19 disease. • Also Phase I/II in Japan, and South Africa. As with all other candidates, the Phase III trial is not aligned with WHO solidarity guidelines. Multiple Phase II/III trials[11] • Phase II/III underway in the United States, Brazil, United Kingdom, India and Russia. • Subjects 18-70 years of age. • Media statements about results from Phase III trials released in Nov 20 (discussed below). Statements about Phase III trials in November 2020 • AstraZeneca and the University of Oxford released information about Phase III clinical trial results on 23 November. • The timing of these trials is not known at this stage, but AstraZeneca inform us that they will work with regulators on the best approach for further evaluation.

[9] Commenced on 23 April 2020 with interim phase 2 results published in the Lancet, July 2020.
[10] Study NCT04324606. Study NCT04400838. Study NCT04444674.
[11] Commenced on 30 May 2020 to be completed in mid-late 2021.

Safety profile: • Aggregate and non-aggregate (taking into account population groups) • Side effects and adverse reactions	Critical	As confident as we can be from early information	***Science overview***[12] Previous (unlicensed) vaccines based on the viral platform (ChAd rather than ChAdOx1) are considered by the developer to have a good safety profile in humans. These include vaccines against malaria, HIV, influenza, hepatitis C, tuberculosis, Ebola, and others. The particular vector has only been used in a MERS vaccine. Similarly to other candidates this vaccine is reactogenic. Phase I/II data also show more than 50 percent of participants experiencing each of fatigue, headache, malaise and muscle aches. Systemic reactions were less common in those older than 55 years, than in younger adults. Reactogenicity has been observed in early trials of all key vaccine candidates, which may have an impact on the implementation of the immunisation programme, as well as potentially reducing the acceptance of COVID-19 vaccines and BAU immunisation programmes. There is also the potential impact of people with adverse reactions presenting similarly to COVID-19 symptoms and subsequent downstream effects on testing, isolation, contact tracing and productivity. Testing is being conducted on whether paracetamol is useful as a standard part of vaccination schedule to reduce reactogenicity. There have been two neurological serious adverse events after vaccination in Phase III trials. The Data & Safety Monitoring Board has determined these were unlikely to be related to the vaccine, but more information is being sought from the developers as both occurred approximately two weeks after a dose of vaccine and it is difficult to exclude the possibility that this vaccine triggers an exacerbation of pre-existing but undiagnosed neurological conditions[13]. There were no hospitalised or severe cases reported in anyone who received the vaccine. As with other COVID-19 candidate vaccines, there is the potential for safety issues including disease enhancement after vaccination. In human and pre-clinical studies, a T-helper 1 dominated response was seen.[14]

[12] Taken from Panel's overview dated and commentary, both dated 25 November 2021.

[13] One serious but unspecified adverse event was also seen in a phase 1 trial of MERS vaccine using the same ChAdOx1 platform, but was not considered to be related to the vaccine.

[14] T-helper 2 dominated responses are believed likely to lead to more vaccine-related adverse outcomes.

			Disease enhancement, if it occurs, is likely to be seen a long time after vaccination (possibly over a year) so safety follow up in trials and post-licensure is important.
Effectiveness • Aggregate and non-aggregate	Critical	Shows some promise, but will be essential to see data from Phase III results.	***Science overview***[15] *The vaccine is immunogenic* The interim Phase III data builds on earlier Phase I/II peer-reviewed trial results, which have shown that the vaccine induces strong antibody and white blood cell immune responses across all age groups, including older adults. The developer considers it may also reduce transmission, as well as protect against disease, through a reduction in asymptomatic infection, although this claim needs to be validated. Interim Phase III data indicates the candidate may also have other specific advantages. The vector in this vaccine is not based on a human virus. This means that pre-existing immunity (and theoretical risk of dampening response to the vaccine) in humans is likely to be lower for this vaccine compared to COVID-19 vaccines based on a human virus vector. However, it is not yet known if memory immune responses will develop against the non-human vector post-vaccination, and whether this will affect later boosters.[16] Previous (unlicensed) vaccines based on this platform are considered by the developer to have good immunogenicity in humans.[17] It is not clear if immunogenicity assays will be comparable to those used by other vaccine developers, and whether it will be possible to compare immunogenicity across vaccines (this issue is common to all candidate vaccines). *Efficacy* In non-human primate challenge studies, the vaccine reduced viral replication in lungs but not in the upper respiratory tract, and if this also occurs in humans, it could translate to

[15] Taken from Panel's overview and commentary, both dated 25 November 2021.
[16] The developers did not mention if immune interference to the virus vector is anticipated after widespread vaccination using this vector.
[17] These include vaccines against MERS, malaria (good T-cell response, insufficient neutralising antibody), HIV (no details on immunogenicity in publication), influenza, hepatitis C (poor immunogenicity in hepatitis C patients), tuberculosis, Ebola, and others.

			efficacy against clinical disease with lower/absent efficacy against infectiousness. The panel also queried the use of a placebo as a comparator in efficacy trials as the lack of local reactions might effectively unblind the studies. Interim analysis of the Phase III trial indicates a 70.4% vaccine efficacy, based on 131 cases of COVID-19 and combining data from 2 different dosing regimens (both received 2-doses one month apart, but one arm received a halved first dose). The half-dose followed by full-dose regimen had higher efficacy (90%) than the two full-doses regimen (62%), although the precision of these point estimates is unclear, so they may not be statistically distinguishable. It is critical to first review the detailed analysis of the completed study with greater participant numbers in order to see whether this difference is confirmed. In the last two weeks Pfizer, Moderna and AstraZeneca have made media statements about the efficacy of their vaccine candidates. We should be cautious about drawing conclusions from these statements about the suitability of their vaccines for our preferred portfolio because: • the statements are media messages rather than clinical data about the safety and efficacy of the candidates and there is little that can be concluded other than there appears to be some efficacy • the claims of efficacy are not directly comparable between the candidates • regulators will need to view data to assess efficacy and safety, including to enable comparisons to be made between the candidates. The main regimen, consisting of two full doses given at least a month apart, appeared to be 62 percent effective. But in a smaller group of participants who (due to a dosing error) received a half dose followed by a full second dose, the vaccine appeared to be 90 percent effective. The half-dose/full-dose regimen looks promising, but there have been too few cases of COVID-19 in the trial to make reliable judgements about the statistical significance of the results at this stage. Participants in the sub-group that received the half-dose/full-dose regimen were all aged under 55, which may have contributed to the high efficacy observed in that group. Further clinical trial results will validate both regimens in a larger number of people, which will provide more reliable information about the efficacy of the two regimens. Care must be

			taken with all interim results, as they are based on relatively small numbers and ongoing trial data will provide greater understanding of vaccine performance. The Phase III trial is assessing asymptomatic infection (by SARS-CoV-2 nucleocapsid assay) and so vaccine information about efficacy against asymptomatic infection should also become available.
Ease of distribution:	High	Distribution requirements are generally in line with norms. Like other reactogenic vaccines there may be some issues with vaccine acceptance	***Deployment requirements are within general expectations for COVID-19 vaccines*** *Administration of vaccine* • Two dose regimen given by intramuscular injection one month apart. Two different regimes are being tested. Interim Phase III clinical trials data suggest that the best immunological response may be achieved if the first dose contains half the product of the second dose. It is not yet known if the dosing regimen would follow this format, but a regimen with this type of variation could increase administrative complexity. • The vaccine is distributed using standard 2-8 degree Celsius cold chain methods. • May require paracetamol at administration to address reactogenicity. *Presentation / packaging* • Liquid <10 ml multidose glass vial, each provides up to ten 0.5 mL doses. • Does not contain any preservatives[18]. • The number of vials per pack remains under discussion. AZ have noted that packaging requirements including location of temperature monitors will be covered in the specifications for the product. *Distribution and storage:* • Currently, the vial should be used within four hours of opening (work is ongoing to assess if this can be extended). • Must be kept in original packaging until use to prevent prolonged light exposure. • Would be distributed and stored at 2-8°C. • Not to be frozen. • Supplier will deliver product by separate instalments.

[18] Use of preservatives increases vaccine hesitancy.

			• Will distribute to AZ distribution facility. • Supplier has indicated that the shelf life of the product starts when the vial fill occurs and given the time to ship, import, release, and other factors, it is not possible to deliver with "full approved shelf-life remaining". • The data on shelf life is evolving. However, the agreement proposes a minimum shelf life of three months at the time of delivery, or a longer period if further studies indicate longer shelf stabilities.
Availability and access			
Production: • Confidence in developer • Reliability of supply chains for raw materials • Capacity (including domestic manufacturing and flexibility) • Delivery schedules • Technology platform • Licensing arrangements	Critical	Confidence in planned production	***The supplier is new to vaccine development but has partnership and resources to address gaps in capability and experience*** • Large pharmaceutical firm with general expertise, but vaccines is a new area. • Have partnered with Oxford University for development. • Have resources to buy in development expertise and to manufacture the vaccine. ***There is reasonable confidence in the ability of the supplier to manufacture a quality product in the quantities proposed*** • It is reported that AstraZeneca has signed multiple manufacturing and supply agreements globally, including in the United States, United Kingdom, South Korea and Brazil, resulting in a target to make over 2 billion doses of the experimental vaccine. • AstraZeneca's website states it is building supply chains in parallel across the world. This includes the United Kingdom, Europe, Serum Institute of India (1 billion doses for low and middle-income countries), and CSL in Australia. • Large available resource means confidence is higher than for other smaller companies who, like AstraZeneca will need to contract out manufacturing. • There has been some media comment about manufacturing and testing errors that resulted in the half-dose/full-dose regimen being given to some participants. These types of errors are not unusual in clinical trials of pharmaceutical products, with risks expected to increase for products being manufactured and tested at speed. • AstraZeneca's situation is not likely to be an isolated case, and we have observed that other suppliers, such as Pfizer, are signalling delays in the availability of information about their manufacture and quality control processes. • AstraZeneca had advised that they consider that there is strong merit in continuing to further investigate the half-dose/full-dose regimen. They are evaluating the data

			and will work with regulators on the best approach for further evaluation, however we do not know the timing of the additional trials, or whether the trials and the regulatory approval of the second regimen would be completed before our vaccines are delivered. • Existing clinical trials will continue as planned, and AstraZeneca is preparing for regulatory submissions based on these trials. • New Zealand's supply is likely to come from the United States. The drug substance is expected to be produced by Catalent Inc., and drug product fill and finish at AstraZeneca's West Chester facility. • The Supplier has provided site locations for drug substance, drug product and packaging sites for EU Supply. *Delivery schedule* • As with all of the Group A candidates, delivery expectations are optimistic. • Expected delivery dates to New Zealand are still being investigated, but supplier has suggested starting as early Q2 2021. • Has advantage that the whole delivery is expected to occur over a relatively short span of time, and therefore immunisation can happen over a short period. • 9(2)(ba)(i), 9(2)(ba)(ii) • 9(2)(ba)(i), 9(2)(ba)(ii) *Technology platform* • Non-replicating viral vector, based on a recombinant simian-adenovirus-based vector. *Regulatory issues* • This vaccine has an advanced plan for licensure with EMA (European licensing), with a rolling review and a target completion date for the data package being the end of 2020 and possible licensure in January 2021. There are also ongoing processes with MHRA (United Kingdom, Brexit adding complexities) and FDA (United States). • Clinical development done in discussion with EMA. • Started process for environmental risk assessment (in EU), and meeting labelling requirements.

			• Medsafe have agreed to a rolling submission from AstraZeneca, to make the best use of information as it becomes available. The timeframe for data to be sent to Medsafe have not been confirmed, but AstraZeneca suggest a full set of data will not be available until next year. • As sections of the EMA rolling submission process are completed, they will share them with New Zealand (Medsafe has negotiated that it will be at the same time as in Australia). • The time required to achieve regulatory approval is to a large extent dependent on the timeliness and quality of the information provided by suppliers to regulators. • Trialing of the half-dose/full dose regimen is not known and regulatory approval may not be obtained until after New Zealand has received it's deliveries. • Have started rolling submission approach in EU and looking at approval there by January. • Have talked to Therapeutic Goods Administration (TGA) in Australia and in principle have agreement to follow same sort of process, and commenced discussions about process with Medsafe. • Will be working with Medsafe on manufacturing consistency and Good Manufacturing Practice (GMP) compliance with Chemistry, Manufacturing and Control (CMC). *Vaccine acceptability* • Pending decision by the Environmental Protection Authority, but being a replication-defective adenoviral vector, this may not be a genetically modified organism • Preservative free nature has positive implications for vaccine-hesitant groups.
Contracting: • Type of purchasing agreement • Partnership with other countries • Options to manufacture • COVAX implications	High	Satisfactory contractual terms negotiated	***Supply Agreement is satisfactory and meets our negotiation priorities***[19] 9(2)(ba)(i), 9(2)(ba)(ii)

[19] See summary of negotiation priorities.

			9(2)(a) ***New Zealand has expressed an interest in purchasing additional courses through the COVAX Facility*** • We have expressed interest in purchasing the first three candidates offered through the Facility: Pfizer, AstraZeneca, and Sanofi/GSK. • COVAX Facility has purchased 150 million vaccines.
International risk assessment: • Health, economic and social impacts of pandemic (impacts on demand and availability) • State support for development and manufacturing • Sovereign hoarding • US election • COVAX commitments	High	Low	***There are some international risks with the proposed purchase, but not enough to preclude the purchase***[20] • There is some distributional risk and otherwise very low reputational and geopolitical risk associated with purchase of this candidate. These international risk considerations should not preclude purchase of this candidate, subject to ongoing monitoring to ensure adequate measures are in place to mitigate distributional risk. A review of this assessment should be undertaken following the United States presidential election in November 2020. • The Chief Executive of the Serum Institute of India (SII) has said that it will prioritise distribution of Oxford/AstraZeneca's vaccine to India over the rest of the world, although SII is yet to enter into an official purchasing agreement with the Indian government. Earlier this year AstraZeneca and SII entered into a licensing agreement, with SII agreeing to supply one billion doses to low-and middle-income countries, including India. The CE has now said that 90% of SII's doses will likely go to the Indian government at around US$3 a dose. SII has produced 40 million doses of the vaccine already and expects to make at least 100 million more doses by January. • No foreseeable reputational risks associated with purchasing from the supplier • Little geopolitical/propaganda risk.

[20] See International risk assessment produced for taskforce dated October 2020.

			• 6(a) [redacted] • Intellectual property, information technology and privacy risks are not a significant concern.
Number of courses			***Number of courses is agreed*** • 3.8 million courses have been agreed. This represents two manufacturing batches and is the amount available to New Zealand at the moment. • Additional vaccines may become available through the COVAX Facility. • The agreement allows that prior to end of Global Pandemic End Date, New Zealand can order additional supplies, on new terms to be agreed.
Cost per coarse		9(2)(ba)(i), 9(2)(ba)(ii) [redacted] Lower pricing may be offered to developing nations.	9(2)(ba)(i), 9(2)(ba)(ii) [redacted] ***Tiered global pricing may be offered*** • The CE of the Serum Institute has said that 90% of vaccines manufactured by the Institute will likely go to the Indian government at around US$3 a dose.
Contribution to portfolio balance		Good fit with portfolio strategy	
Diversity of vaccine platforms		2nd option for platform,	***This is the second viral-vector broad population vaccine in the portfolio***

		which has timing advantages	• Provides a 2nd option in a platform type that is likely to be available in the timeframe required for the immunisation programme. • Advanced economies using the same purchase frameworks as us also have this overlap. This could be due to the earlier development of vaccines using this platform.
Diversity of suppliers		Achieved	***Different suppliers to other vaccine target vaccines in the preferred portfolio*** Manufacturing locations are likely to be in the United States, so same location as candidates as Pfizer and Janssen.
Sufficient coverage, without risk of over-purchase		Achieved, further vaccines will be sought through the COVAX Facility	Early results suggest it has the potential to protect those aged 55 and over more effectively than some other candidates, particularly in the 60-70 year age group. AstraZeneca can foresee no specific issues which would impact distribution of this vaccine to Pacific nations at this stage, other than the need for refrigeration (which is less challenging than the frozen distribution required for some other candidates).
Early access/Delivery timeframes		Likely to be delivered within required timeframes	Likely to be delivered at a time suitable for the immunisation programme for 2021 and 2022. Same level of optimism as rest of Group A about delivery dates.

Other matters not part of the framework analysis		
Suitability for different population groups	◆	Unlikely to be able to determine this at the time decisions are made whether to enter APA.
Duration of immunity	◆	Unlikely to be able to determine this at the time decisions are made whether to enter APA.
Immunity type	◆	Unlikely to be able to determine this at the time a decision is made whether to enter APA. Animal challenge trial indicates that vaccine is not fully protective (i.e. pointing to non-sterilising immunity").

Multi-lateral or bilateral		Bilateral
APAs concluded by New Zealand		Committed to purchase of 750,000 vaccines from Pfizer, and in negotiation for additional doses. Agreed to terms to purchase five million vaccines from Janssen.

1 December 2020

BRIEFING

Commitment to purchase COVID-19 vaccines from Pfizer Inc.

Date:	2 October 2020	**Priority:**	Urgent
Security classification:	Sensitive	**Tracking number:**	2021-0996

Action sought		
	Action sought	**Deadline**
Rt Hon Jacinda Ardern **Prime Minister** Hon Grant Robertson **Minister of Finance** Hon Dr Megan Woods **Minister of Research, Science and Innovation** Hon Chris Hipkins **Minister of Health**	**Agree** to commit New Zealand to binding terms that will form the basis of a Definitive Agreement with Pfizer Inc. to purchase 750,000 courses of a potential vaccine against COVID-19.	5 October 2020

Contact for telephone discussion (if required)			
Name	**Position**	**Telephone**	**1st contact**
Poppy Haynes	Manager, COVID-19 Vaccine Purchase, MBIE	9(2)(a)	✓
Maree Roberts	Deputy Director-General, System Strategy & Policy, MoH	9(2)(a)	
Bhagee Ramanathan	Principal Policy Advisor, MBIE	9(2)(a)	

The following departments/agencies have been consulted
PHARMAC, MBIE, MoH, MFAT, Treasury, DPMC

Minister's office to complete:

- ☐ Approved
- ☐ Noted
- ☐ Seen
- ☐ See Minister's Notes
- ☐ Declined
- ☐ Needs change
- ☐ Overtaken by Events
- ☐ Withdrawn

Comments

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Commitment to purchase COVID-19 vaccines from Pfizer Inc.

Date:	2 October 2020	**Priority:**	Urgent
Security classification:	Sensitive	**Tracking number:**	2021-0996

Purpose

Seek approval to commit to binding terms that will form the basis of a Definitive Agreement to purchase 750,000 courses of a potential vaccine against COVID-19 from Pfizer Inc., which is expected to be delivered in the first half of 2021 (subject to the successful development and regulatory approval of the vaccine).

Executive summary

Background

The global demand for COVID-19 vaccines continues to be high, with capacity to manufacture successful vaccine candidates heavily constrained worldwide. This constraint is expected to continue for some time.

In May, Cabinet approved the COVID-19 Vaccine Strategy [CAB-20-MIN-0229.01] with the objective of ensuring access to a safe and effective vaccine. In August, Cabinet established a tagged contingency of up to $600 million [CAB-20-MIN-382] for purposes including the advance purchase arrangements of potential COVID-19 vaccines.

You have agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (MBIE: 2021 – 0662 refers). The purchasing strategy aims to pre-purchase a number of potential vaccines at a stage where they still carry a high development risk. We have early information about their performance, information about manufacturing processes and plans, and other countries' conclusions on decisions to enter into advance purchase arrangements. Money spent on advance purchases may be lost if the development is unsuccessful, or if the candidate is found to be unsuitable for deployment as part of the Government's preferred immunisation strategy. This is the cost of attempting to secure supply in the current global context.

Opportunity to acquire a candidate with a relatively early delivery date

As part of work to construct the portfolio we have been negotiating with the suppliers of priority vaccine candidate targets and now have an opportunity to purchase 750,000 courses of an mRNA vaccine from Pfizer for a total of 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]. If the development is successful and regulatory approval received, Pfizer believes it can begin to deliver in the first half of 2021. High global demand and constrained supply mean this is a highly time limited offer, 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

We have taken advice from Bell Gully, commercial advisors, and an independent science advisory panel, during the negotiation. PHARMAC has also been involved. The negotiated offer is in the form of a binding term sheet and attached in Annex One.

We recommend accepting the offer because this vaccine candidate has the potential to provide early access to a safe and efficacious vaccine that can be delivered and used in New Zealand in the first part of 2021. Early access is a key requirement for our portfolio.

The supplier and the vaccine candidate satisfy the requirements in the vaccine purchase framework, and suitable commercial terms have been negotiated. In summary:

- Pfizer has a proven track record for their ability to develop, manufacture and deliver a product that meets New Zealand's quality standards, and the vaccine is likely to be among one the earliest available for regulatory review and use in New Zealand. A number of comparator countries, such as Canada, the UK and the US already have advance purchase agreements with Pfizer. Current information on safety and efficacy show that the vaccine is promising and developing in line with expected performance norms. There are logistical and delivery issues that are in the process of being resolved.

- The binding terms negotiated with Pfizer are in line with the negotiating priorities approved by the Vaccine Strategy Taskforce.

- 9(2)(ba)(i), 9(2)(ba)(ii) we are advised that the negotiated indemnity is in practice very close to the scope of ACC, and risks are relatively low overall. We will provide a business case to the Treasury on the indemnity provision. The Minister of Finance's agreement will be sought at the time the Definitive Agreement is finalised.

Contribution to portfolio

9(2)(ba)(i), 9(2)(ba)(ii) there is inherent risk with expected delivery dates of all COVID-19 vaccine candidates. However, at this stage it appears to be the only viable and globally available candidate with a prospect of delivery and potential to be approved for use in New Zealand in the first part of 2021. Early access to a safe, efficacious vaccine will be key in prioritising the protection of New Zealanders at highest risk of infection. 9(2)(ba)(i), 9(2)(ba)(ii) Also, in our negotiations, no other developer has offered delivery of vaccines as early as Pfizer have. As well as not having access to an early vaccine, not including the Pfizer candidate in the portfolio risks reducing the technology diversity in the portfolio.

This vaccine is required to be stored at -70 degrees Celsius, which makes it unlikely to be suitable for delivery in Polynesia. Other APAs being negotiated are more like to present better options for delivery in Polynesia.

Regulatory approval

We will take delivery of supplies once regulatory approval is obtained, so safety and effectiveness are necessary conditions that will be satisfied before these vaccines are available to be deployed. We understand from Medsafe that Pfizer have provided pre-submission information and is expected to make an application near the end of the year. Medsafe advise they are increasing their resources in order to expedite the evaluation of a number of concurrent COVID-19 applications, while ensuring that vaccines meet acceptable standards for efficacy, safety, and quality.

Next steps

Subject to your agreement to the recommendations in this briefing the Director-General of Health, on behalf of the New Zealand Government, will sign the binding term sheet attached at Annex One. Upon the execution of the term sheet we will negotiate the Definitive Agreement. Your approval will be sought for the terms of that arrangement and for the drawdown of 9(2)(ba)(i), 9(2)(ba)(ii) from the vaccine purchase contingency for the advance payment.

We hope to reach agreement on purchase terms and conditions for two other vaccine candidates within the next two weeks.

Subject to your agreement to execute the binding term sheet, we will work with Pfizer to plan communications and publicity opportunities, including 'bundling' a number of announcements.

Recommended action

The Ministry of Business, Innovation and Employment, and the Ministry of Health recommend that you:

a) **Note,** in May Cabinet approved the COVID-19 Vaccine Strategy [CAB-20-MIN-0229.01] with the objective of ensuring access to a safe and effective vaccine to implement the Government's preferred immunisation strategy at the earliest possible time.

Noted

b) **Note,** in August Cabinet established a tagged contingency of up to $600 million [CAB-20-MIN—382] for purposes including the advance purchase arrangements of potential COVID-19 vaccines, noting that early investment is urgently needed to secure options for future access to potential vaccines.

Noted

c) **Note**, an unprecedented global health crisis continues and the New Zealand population remains almost totally susceptible to COVID-19 due to our successful elimination strategy.

Noted

d) **Note**, the global demand for COVID-19 vaccines continues to be high, and capacity to manufacture successful vaccine candidates is heavily constrained worldwide, and likely to be constrained for some time.

Noted

e) **Note**, last month joint Ministers agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (MBIE 2021 – 0662 refers).

Noted

f) **Note**, we have been assessing vaccine candidates prioritised by the Vaccine Taskforce against the purchase framework, taking advice from legal, commercial and science advisors to negotiate terms for the advance purchase of those candidates.

Noted

g) **Note**, we have negotiated an offer from Pfizer for the purchase of an mRNA vaccine candidate that is likely to be in the group that is earliest available.

Noted

h) **Note**, the vaccine candidate may have the benefit of timeliness, and could potentially be a key part to managing our health care services, and protecting the population from new incursions of COVID-19 through the vaccination of those most at risk of contracting and spreading COVID-19.

Noted

i) **Note**, the negotiations have been carried out with advice from legal, commercial and science experts. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

Noted

j) **Agree**, subject to the agreement of the Minister of Finance to provide an indemnity to Pfizer Inc. and BioNTech, to commit to binding terms that will form the basis of a

Definitive Agreement with Pfizer Inc. to purchase 750,000 courses of COVID-19 vaccines that are attached in Annex One.

Agree / Disagree

k) **Agree**, subject to your agreement to recommendation j) above, the Director-General of Health sign the binding term sheet on behalf of the New Zealand Government to give effect to that decision.

Agree / Disagree

l) **Note**, if you agree to the recommendation in j) above we will seek your approval for the conclusion of a Definitive Agreement with Pfizer Inc. and to drawdown 9(2)(ba)(i), 9(2)(ba)(ii) from the "Minimising the health impacts of COVID-19 – tagged operating contingency (tagged contingency)" for the advance payment to Pfizer Inc.

Noted

m) **Note**, a further drawdown of 9(2)(ba)(i), 9(2)(ba)(ii) will be required next year from the "Minimising the health impacts of COVID-19 – tagged operating contingency (tagged contingency)" to fund the 'remainder payments' to Pfizer Inc.

Noted

n) **Note,** you have received a paper from the Ministry of Health requesting approval to draw down $65.3 million from the tagged contingency to urgently purchase critical resources for the immunisation programme, including resources to support vaccines of the nature that would be supplied under the proposed agreement. (MoH 20201744 refers).

Noted

o) **Note,** other negotiations for the advance purchase of COVID-19 vaccines are underway and two are expected to be concluded in the next few weeks.

Noted

Rt Hon Jacinda Ardern
Prime Minister
...../...../.....

Hon Grant Robertson
Minister of Finance
...../...../.....

Hon Dr Megan Woods
Minister for Research, Science, Innovation
...../...../.....

Hon Chris Hipkins
Minister for Health
...../...../.....

Maree Roberts

Deputy Director General, Ministry of Health

Ministry of Health

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

Dr Peter Crabtree

GM, Science, Innovation, International, MBIE

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

Background

Global demand for vaccines remains high

1. The global demand for COVID-19 vaccines continues to be high, and capacity to manufacture successful vaccine candidates is heavily constrained worldwide. This is expected to be the case for some time. Globally, there are around 200 vaccine candidates under development. All vaccine candidates are still undergoing clinical development and trial and therefore carry a high level of development risk.

2. An unprecedented health crisis continues worldwide, and the New Zealand population remains almost totally susceptible to COVID-19 due to our successful elimination strategy.

Ministers have previously agreed to a purchasing strategy and a framework to guide purchase decisions

3. In May, Cabinet agreed the purchasing strategy to support acquisition of COVID-19 vaccines [CAB 20-MIN-0382]. This recognised the need for Government to build a portfolio of vaccine investments through the urgent negotiation of a number of advance purchase agreements (APAs) for safe and effective vaccines that are likely to be approved by Medsafe in a timely manner for use in New Zealand.

4. In August, Cabinet established a tagged contingency of up to $600 million [CAB-20-MIN-382] for purposes including the advance purchase arrangements of potential COVID-19 vaccines, noting that early investment is urgently needed to secure options for future access to potential vaccines.

5. You have previously agreed a decision-making framework to assess vaccine candidates to guide acquisition choices (MBIE: 2021 – 0662 refers). The application of the framework criteria is intended to ensure that negotiations with vaccine developers aligns with New Zealand's overall objectives for responding to COVID-19 and recognises that, our decisions on advance purchasing will be made on the basis of early-stage information.

6. Once concluded, APAs would commit New Zealand to the purchase of vaccines, conditional on successful clinical trials of the vaccine candidate. The subsequent decisions to use these vaccines in New Zealand would be subject to New Zealand regulatory approval, and their suitability for deployment as part of New Zealand's immunisation strategy.

Target candidates have been shortlisted but no APAs have been concluded

7. From the vaccine candidates globally under development, the COVID-19 Vaccine Strategy Taskforce have prioritised a set of targets for the conclusion of APAs for New Zealand.

8. With the prioritisation of vaccine candidates and the decision making framework in place, officials have obtained additional information from vaccine developers as well as advice from experts to build detailed assessments of the priority target candidates.

9. No APAs have been concluded by New Zealand so far. Discussion with international counterparts and media announcements indicate a number of like-minded countries have reserved large quantities of vaccine doses in advance purchase arrangements.[1]

New Zealand has committed to the Options Arrangement offered by the COVAX Facility

10. Earlier this month New Zealand entered into a binding commitment to the Options Arrangement available through the COVAX Facility (briefing MBIE-2021-0858 refers). A drawdown of $35 million will be made from the tagged contingency of $600 million to provide

[1] The UK has bought up to 185 million courses, if Janssen's candidate can be successfully delivered in a single dose. This is 2.8 times the amount required to immunise their population. The EU has up to 740 million courses (with options for additional purchases), which is 1.6 times the amount required to immunise their population of 446 million. Canada has bought around 150 million courses, which is 3.9 times the courses required to immunise their population.

for this commitment. Around 70 self-financing economies have also made commitments to the Facility, with further expected to sign. The COVAX Facility is continuing to be developed. Participation in the facility is an integral component of our vaccine purchase strategy and complements our bilateral purchase arrangements and spreads risk by providing an opportunity to access a potentially broader portfolio of vaccines.

We have an opportunity to purchase 750,000 courses of a mRNA vaccine developed by Pfizer Inc.

Pfizer Inc. has offered to sell New Zealand 750,000 courses of its COVID-19 vaccine, which is anticipated to be delivered during 2021

11. Pfizer Inc. (supplier) has offered New Zealand 750,000[2] courses (1.5 million doses) of its vaccine candidate (known as BNT 162), an mRNA[3] vaccine. Subject to successful trials and regulatory approval, the supplier expects to deliver the vaccine over the first three quarters of 2021[4]. The vaccine will cost 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] The vaccine consists of two doses[6], each delivered intramuscularly 28 days apart.

12. RNA vaccines have the advantage of speedy development – they can be quickly designed and manufactured. However, they have never been approved for human use outside medical research.

13. Negotiations with this supplier have been prioritised because there is high confidence in the ability of the supplier to develop, manufacture and deliver a vaccine to prescribed quality standards. Also, subject to successful clinical trials, this vaccine is likely to be within the first group of COVID-19 vaccines to become available for wide use (i.e. beyond emergency use).

14. While there are inherent risks to the delivery time of all vaccine candidates, the potential timeliness of the candidate could allow early vaccination of 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. It may also be considered for use in outbreak management.

15. The development of a prioritisation framework in conjunction with the COVID-19 immunisation strategy will determine how the Pfizer vaccine will be used to support the Government's overall elimination strategy and equity considerations.

16. We understand the supplier has begun engagement with Medsafe with a view to providing early information as a pre-curser to an application for regulatory approval.

17. The offer from Pfizer is made in the form of a binding term sheet, and is attached as Annex One. It contains the essential terms of the arrangement that once executed commits both parties to endeavour in good faith to conclude a Definitive Agreement within four weeks. The Definitive Agreement is likely to contain other non-essential terms typically found in pharmaceutical supply and funding agreements, including terms in past agreements between

[2] 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

[3] RNA vaccines contain a strip of genetic material within a fat bubble. Once inside the cell, the RNA generates a protein found on the surface of the virus. The immune system, presented with the protein, learns to recognise the virus.

[4] 9(2)(ba)(i) & (ii) [redacted]

[5] 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

[6] Most COVID-19 vaccines are likely to require a second dose within a strictly prescribed timeframe.

9(2)(ba)(i) & (ii)

18. It is Pfizer's expectation that the binding term sheet is executed before negotiations can commence on the Definitive Agreement.

19. If New Zealand does not conclude an APA with Pfizer at this time, it is likely that we will lose the ability to purchase this vaccine for at least a further 18 months (with the exception of what might become available through the COVAX Facility if Pfizer participates in that arrangement). This is due to the high global demand for vaccines, particularly those expected to be delivered early.

We recommend purchasing the Pfizer vaccine

20. We seek your approval to purchase the available doses of the Pfizer vaccine. There is a limited window of time in which Pfizer will reserve the doses for New Zealand, 9(2)(ba)(i), 9(2)(ba)(ii) We have analysed the offer against the vaccine purchase framework previously agreed by joint ministers and found it satisfies the criteria in the framework. We believe there is a strong rationale to sign the binding term sheet because:

    a. Subject to successful clinical trials, this vaccine is likely to be the earliest safe and efficacious vaccine we have access to, and would be a critical resource should we wish or need to vaccinate key groups in the first half of next year.

    b. The logistical complexity created by the vaccine's need for ultra-cold (-70°) storage is surmountable, and is outweighed by the potential benefit of having early access to a COVID-19 vaccine.

    c. We have negotiated terms that we believe are satisfactory, and are in line with global trends for COVID-19 vaccine advance purchase arrangements.

    d. We have confidence in Pfizer's ability to develop, manufacture and deliver a vaccine to prescribed quality standards.

    e. Comparator countries have advance purchase agreements with Pfizer to secure early access to vaccines. Together, the US, UK, Canada and Japan have advance purchase arrangements with Pfizer for around 135 million courses of this vaccine candidate. We understand the EU, Australia, and the COVAX Facility are also negotiating advance purchase arrangements with Pfizer. Comparator countries have used similar frameworks to ours, using their experts to interrogate the early science results, trial designs and manufacturing programs.

    f. We have undertaken our own framework analysis, using advice from an independent science review panel that has led us to the same position.

    g. Without this candidate our portfolio may lack two important components. The portfolio should include a portion of vaccines that can be obtained at the earliest possible time. Also, the portfolio should include vaccines based on a range of technology platforms, both relatively untested such as RNA and those that use more traditional platforms and technologies. The safety and efficacy of the other RNA candidate in the target group is not as promising.

21. Below and in Annex Three we set out our analysis against the framework more fully.

The vaccine purchase framework seeks to align purchase decisions with the vaccine purchase strategy using the information available at the time

22. The framework is summarised in Annex Two. Its broad approach considers:

23. Vaccine performance considers criteria such as safety profile, effectiveness and ease of distribution across the population as a whole and to particular population groups. Availability and access considers factors such as confidence in production, contractual terms and geopolitical dynamics and international risks.

24. Ideally, New Zealand will only want to enter into advance purchase agreements that meet minimum standards around safety and effectiveness. However, given intense global competition for vaccines in a context where there will be continuing production constraints in the short to medium term, we will need to make decisions whether to enter into binding agreements based on the best information available at the time. In advance of full vaccine development and regulatory approval and in the absence of final data, the framework uses proxies to help inform choices.

From the information available now, overall the offer satisfies the criteria in the vaccine purchase framework

25. A multi-agency approach was taken in negotiations to strengthen the level of interrogation. We have taken advice from Bell Gully, as well as from an independent scientific and clinical review panel, to help inform our analysis of the offer and information about the vaccine candidate, the developer and the supplier. Overall, we consider that the criteria in the framework have been met to a satisfactory level. That analysis is discussed below, with further detail attached as Annex Three.

Satisfaction of vaccine purchase framework criteria

	Criteria	Importance	Assessment of criteria	Level of satisfaction of criteria*
Target priority	**Within priority group, and confidence in ranking**	Group A, high importance	Group A, and high confidence	✓ ✓ ✓
	Confidence in priority ranking	High	High confidence	✓ ✓ ✓
Performance	**Safety profile**	Critical	As confident as we can be from information available now	✓ ✓
	Effectiveness	Critical	As confident as we can be from information available now	✓ ✓
	Ease of distribution	High	Some logistical and training complexities, with cost and risk attached	✓
Accessibility	**Production**	Critical	Confident	✓ ✓ ✓
	Contracting	High	Confident	✓ ✓ ✓
	International risk	High	Low risk	✓ ✓ ✓

	Comparable price offered to others	High	Confident	✓ ✓ ✓
Portfolio	**Portfolio fit**	Critical	Good fit with portfolio strategy	✓ ✓ ✓

*** Key:** ✓ ✓ ✓ high satisfaction of criteria; ✓ ✓moderate satisfaction of criteria; ✓ satisfaction of criteria; • criteria not met.

We have high confidence in the vaccine candidate's priority target ranking and in the developer and supplier

26. The Pfizer candidate is ranked in the highest priority group within the targets selected by the Taskforce. There is high confidence in Pfizer's and BioNTech's science-to vaccine capability. Their speed and scale are strengths. Pfizer has a very strong track record in producing safe and efficacious human vaccines for use globally and is one of the world's largest pharmaceutical firms.

We have confidence in the vaccine candidate's potential performance

27. As is normal at this stage in the clinical trials, limited information is available about the vaccine candidate's performance. From what is possible to know now, the vaccine candidate shows some promise in terms of early-stage clinical trial results, and there are no undue safety concerns at this stage. However, there are issues to be worked through in relation to additional equipment and support needed for distributing the vaccine. We will continue to monitor new information about safety and efficacy as clinical trial data becomes available, and progress work to resolve issues in relation to distribution through the immunisation strategy.

28. Specifically, in relation to the three criteria which contribute to vaccine performance:

- Safety – the candidate is in the process of Phase II/III trials so it is not possible at this stage to comment on its safety in relation to New Zealand population groups. The science review panel's advice is based only on information available to date, with more information sought from the supplier when it becomes available. The Panel has concluded that while there are inherent risks with the development of any new vaccine, as well as risks in relation to the new (RNA) technology platform used, there are not likely to be particular issues with trial design in terms of safety (other than relatively short follow up periods observed in all COVID-19 vaccine trials to date). By the time a decision is likely to be taken in New Zealand on whether or not to use vaccine, additional data are likely to be available from other countries.

- Effectiveness – the scientific panel concluded that, from the data presented by the supplier from Phase I/II trials, the results show some promise, with a comparatively strong immune response (antibody production and T cell response) to vaccination observed. They noted, that as expected, the immune response was dose-dependent and reduced in older people. Efficacy results are expected by the end of October.

- Ease of distribution – the need to store the vaccine at -70 degrees Celsius makes this candidate less suitable for wide-scale delivery in New Zealand (and not suitable for the Polynesia), than some other vaccine candidates we are targeting. It is more suited for centralised delivery or to be delivered in large work-places.

29. Planning to meet the logistical and workforce training required to support and administer this candidate is being undertaken within MoH. Approval has been sought to draw down $65.3 million from the tagged contingency to urgently purchase critical resources for the immunisation programme, including resources to support vaccines of the nature that would be supplied under this agreement (MoH 20201744 refers).

30. An important proxy indicator of vaccine performance is the extent to which advance purchase arrangements have been concluded with other comparator countries and with the COVAX Facility. We know that arrangements have been concluded with the US, UK, Canada and Japan for around 135 million courses. We understand the supplier is negotiating with the EU, Australia, and the COVAX Facility. Other countries[7] have also recently concluded APAs with Pfizer.

If the clinical trials are successful, there is high confidence that Pfizer will be able to supply the vaccine to New Zealand

31. Pfizer has a proven track record for their ability to manufacture and deliver a product that meets New Zealand's quality standards. It does not appear that the supplier is selling above their capacity to deliver, and there are no contra-indications on the reliability of supply chains or manufacturing capability from either of their planned manufacturing sites[8]. Similarly to what we are seeing from other vaccine developers, the delivery schedule proposed is optimistic.

Delivery schedules are not certain, they may be delayed and there is no guarantee of a vaccine

32. 9(2)(ba)(i), 9(2)(ba)(ii) This is because vaccines are not yet registered and trials are ongoing. 9(2)(ba)(i), 9(2)(ba)(ii) have been agreed, and were the earliest we were able to procure. While we should be prepared for delays because the delivery timeframe is optimistic and may not factor enough time to enable our regulatory processes to complete a satisfactory assessment, we should remain prepared to administer the vaccine according to the expected delivery schedule. Factors that have an effect on that timing include the supplier's ability to produce the information required by Medsafe.

33. 9(2)(ba)(i) & (ii) 9(2)(ba)(i), 9(2)(ba)(ii)

While likely to be more expensive than vaccines developed on conventional vaccine development platforms that may become available at a later date, the price is comparable to what other countries have been offered

34. Vaccines developed using RNA technology platforms are more expensive than others using more conventional platforms, and while unproven, they have the advantage of enabling faster development and deployment than conventional platforms. 9(2)(ba)(i), 9(2)(ba)(ii) On the whole, parties to advance purchase arrangements are prevented from disclosing purchase price so this information is not available for other APAs concluded by Pfizer. 6(b)(i)

35. Distribution and storage costs are likely to be higher for this vaccine given the requirement to store it at -70 degrees Celsius.

36. Vaccines available later in time, using more conventional technology, are likely to be cheaper. New Zealand is therefore paying a premium for a candidate with potential for early delivery.

The vaccine would play an important role in the portfolio due to potentially being available relatively early

37. The construction of a portfolio of vaccine candidates is intended to manage the risk of failed vaccine development and give us a range of effective vaccines to choose from for our

[7] Most recent announcements were made by Chile and Peru.
[8] In Belgium and Kalamazoo, Michigan.

immunisation programme. This improves the chances of acquiring one of more vaccines that are safe and sufficiently effective for use in New Zealand. The construction of the portfolio therefore requires the selection of vaccine candidates that ensure diversity across technology platforms, suppliers, timeframes, and that address equitable population coverage (including Polynesia). Vaccines for COVID-19 will also have to work alongside public health measures such as testing, border restrictions and therapeutics to manage the pandemic both in transition and over the longer-term. Such considerations will therefore need to be reflected in the construction of a vaccine portfolio and our immunisation programme, and will become more important and nuanced over time as the portfolio develops.

38. Although there is a target set of vaccine candidates identified for initial discussions, there is limited control over the sequencing of purchases because development is at different stages and there are limited stocks available. Negotiations at this stage are focused on obtaining sufficient courses to provide equitable population coverage (in terms of number of courses purchased and ability to deliver across New Zealand and Polynesia), with vaccines spread across a number of different technology platforms, and to obtain early coverage where possible.

39. This candidate is an RNA vaccine. Due to the relative newness of this platform, and truncated clinical trials (which means a reduced ability to identify rare or long-term side effects), we are unlikely to want to immunise the entire population using solely this vaccine candidate. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] We are also pursuing vaccine candidates based on replicating viral vector[9] and protein subunit[10] technologies.

40. The potential benefit offered by the Pfizer candidate, in relation to the rest of our likely portfolio, is timeliness. Early access vaccines could be used 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. Subject to regulatory approvals and successful manufacture and delivery, purchasing this candidate will give us the option of starting our immunisation programme in early 2021. This is earlier than for all other candidates we are in negotiations to buy.

41. This candidate may be suitable for a wide age range of adults. There is no information about the suitability for particular population groups or for those with health conditions.

42. The requirement that this vaccine be stored at -70 degrees Celsius makes it unlikely to be suitable for delivery in Polynesia. Other negotiations are likely to present better options for delivery in Polynesia.

43. As our vaccine portfolio takes shape over the coming weeks, officials will advise you on the overall balance and assessment of the portfolio.

Opportunities for local manufacture of vaccines is sought as a matter of course in negotiations with developers as a means of mitigating supply risks.

44. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] Our other discussions with pharmaceutical companies more generally have revealed that opportunities to contract manufacture vaccines in New Zealand over the next six months are highly unlikely, and therefore domestic manufacturing is not going to support earlier access to COVID-19 vaccines as was initially anticipated. From a strategic standpoint, however, we see benefit in developing the foundations for medium to long term onshore manufacturing capability to potentially support

[9] Viral vector vaccines use a virus that has been engineered to be harmless to ferry a distinctive part of the coronavirus gene into cells, and the immune system learns to recognise it.
[10] Protein based subunit vaccines present an antigen to the immune system without viral particles, using a specific, isolated protein of the coronavirus.

future pandemic preparedness. This will be pursued outside our current APA negotiations. The vaccine candidate is expected to meet the demand in the portfolio for early delivery.

Interaction with supply from COVAX Facility

45. You have agreed to New Zealand's participation in an Optional Purchase Arrangement through the COVAX Facility – a multilateral arrangement (MBIE-2021-0858 refers). Bilateral arrangements, such as APAs are intended to secure delivery of vaccines earlier, of larger quantities, and with greater certainty than by the exercise of options through the COVAX Facility. Although details are still emerging of how the COVAX Facility will operate, it potentially allows New Zealand to either 'double down' on promising candidates purchased 9(2)(ba)(i) & (ii)

46. Availability of the first tranche of vaccine options through the COVAX Facility, expected in late 2021, is capped at 20% of New Zealand's population. Therefore, the usefulness of exercising an option under the first tranche to purchase the vaccine through the Facility will depend largely on expected delivery times. Cover for up to 50% of the population may become available through subsequent distributions, however economies with emergency needs are likely to be prioritised ahead of New Zealand.

Commercial considerations

47. We have taken legal and commercial advice from Bell Gully and others during the negotiation of binding terms with Pfizer. PHARMAC has also been involved in the negotiations. We consider that a good outcome has been achieved. 9(2)(ba)(i), 9(2)(ba)(ii), 9(2)(j)

48. The binding terms proposed are in line with the negotiating priorities agreed with the Taskforce, and we understand they are in line with commercial expectations, with the exception of the indemnity being sought from the Minister of Finance. An outline of how the binding terms compare to the negotiating priorities is included in Annex Four.

49. In summary:

Price	• The price (including proportionate advance payment) and payment conditions are agreed.
Delivery, supply and logistics	• 9(2)(ba)(i), 9(2)(ba)(ii) • 9(2)(ba)(i), 9(2)(ba)(ii) • 9(2)(ba)(i), 9(2)(ba)(ii)
Additional courses and resale	• 9(2)(ba)(i), 9(2)(ba)(ii) • 9(2)(ba)(i), 9(2)(ba)(ii)
Commercial agreement	• Supply terms will be negotiated as part of the Definitive Agreement.

	• 9(2)(ba)(i), 9(2)(ba)(ii)

Pfizer and BioNTech are seeking an indemnity from the Crown

50. As part of the binding term sheet Pfizer and BioNTech sought a [redacted] indemnity for liability 9(2)(ba)(i), 9(2)(ba)(ii) This is because:

    - they are developing it in accelerated clinical trials that are less likely than non-accelerated trials to detect uncommon adverse effects or possible contraindications.[11]
    - 9(2)(ba)(i), 9(2)(ba)(ii)

51. 9(2)(ba)(i), 9(2)(ba)(ii) Overall, we judge the benefit of the APA to New Zealand outweighs the risks and justifies granting the indemnity. Further work is needed on whether and how we pass the indemnity on to Polynesian Countries. Bell Gully has advised that:

    - The need for an indemnity cannot be addressed in another way.
    - The scope of the indemnity is in practice very close to the scope of ACC (i.e. personal injury cover in New Zealand) and that although some risk remains that the indemnity goes beyond what the ACC scheme will cover, for practical reasons the risk to the Crown in this regard is low, and the Crown is able to take certain steps to protect its position as far as possible.
    - 9(2)(ba)(i), 9(2)(ba)(ii)

52. We will provide a business case to the Treasury on the indemnity provision in the Binding Term Sheet. The Minister of Finance can give an indemnity under section 65ZD of the Public Finance Act 1989 (PFA) if it appears to the Minister to be necessary or expedient in the public interest to do so. On the basis of the business case, the Treasury will advise the Minister of Finance on whether the indemnity meets the test in the PFA. Pfizer and BioNTech have indicated that they do not plan to include any further indemnity provisions in the Definitive Agreement.

53. Your agreement to enter into a binding agreement to purchase the vaccines is subject to the Minister of Finance's agreement to provide an indemnity to Pfizer and BioNTech.

Process for concluding the agreement

54. Subject to your agreement to the recommendations in this briefing, and agreement of the Minister of Finance to provide an indemnity to Pfizer and BioNTech, the Director-General of Health, on behalf of the New Zealand Government, will sign the binding term sheet attached at Annex One of this briefing.

55. Upon the execution of the binding terms we will negotiate the Definitive Agreement. The provisions in the binding term sheet include all of the essential terms of the arrangement and

[11] Pfizer and BioNTech will provide Medsafe with full clinical trials information when they apply for regulatory approval. Study designs and regulatory approaches will vary between COVID-19 vaccine applicants, but most trials will be shorter in length and study fewer people than what is typical. The impact is a reduction in the known safety profile of the vaccine (noting that there is some risk in this area even with comprehensive trials).

will be carried through to the Definitive Agreement. Other terms, not inconsistent with the term sheet, but which can be expected in supply agreements of this type, will be included in the Definitive Agreement. Your approval will be sought for the agreement of provisions in the Definitive Agreement and for the drawdown of 9(2)(ba)(i), 9(2)(ba)(ii)

56. The Definitive Agreement is required to be concluded within four weeks of the execution of the binding terms, 9(2)(ba)(i), 9(2)(ba)(ii)

Other negotiations are also likely to be concluded shortly

57. Negotiations are underway with suppliers of a number of other target vaccine candidates. The table below summarises the population coverage being sought, price and delivery times being negotiated for the current five highest priority target vaccine candidates and from the COVAX Facility.

	Courses sought	Platform	Estimated cost	Delivery window	Vaccine distribution
Pfizer	750,000 Partial population coverage (15%)	mRNA: new technology for human vaccines	9(2)(ba)(i), 9(2)(ba)(ii)	9(2)(ba)(i) & (ii)	Very complex: ultra-cold storage required. Each course requires two injections 28 days apart.
Vaccine B	9(2)(ba)(i), 9(2)(ba)(ii)				
Vaccine C	5 million Full population coverage (100%)	Viral vector, with a tested platform	9(2)(ba)(i), 9(2)(ba)(ii)		Straightforward: fridge-stable. Developer currently expects this to be a single-injection regimen.
Vaccine D	5 million Full population coverage (100%)	Viral vector	9(2)(ba)(i), 9(2)(ba)(ii)		Straightforward: fridge stable. Each course requires two injections 28 – 42 days apart.
Vaccine E	5 million Full population coverage (100%)	Protein subunit	9(2)(ba)(i), 9(2)(ba)(ii)		Straightforward: fridge-stable. Each course requires two injections 28 days apart.
COVAX	1 million in first tranche Partial population coverage (20%)	Various	Likely to be average	2021	Various

58. We hope to reach agreement on purchase terms and conditions for two of these candidates within the next two weeks.

Regulatory approvals will be a separate process

59. No COVID-19 vaccine can be used as part of an immunisation strategy within New Zealand until it has received regulatory approval from Medsafe. We have consulted Medsafe to

understand their engagement with Pfizer and likely timeframes for the regulatory review of the vaccine. Medsafe advise that Pfizer have provided pre-submission information and is expected to make an application near the end of the year.

60. Medsafe is actively considering options for expediting the approvals process in order to evaluate a number of concurrent COVID-19 applications, while ensuring that vaccines meet acceptable standards for efficacy, safety and quality.

61. We will also be ensuring that suppliers engage with the Environmental Protection Authority.

Communications and publicity

62. There is strong public interest in the efforts of pharmaceutical companies to develop effective and timely COVID-19 vaccines, and also in which countries would likely have access to a vaccines once they have been developed and approved for use. Given this, and subject to your agreement to execute the binding term sheet, we will work with Pfizer to plan communications and publicity opportunities.

63. There could also be value in 'bundling' a number of APA announcements together, given that the collective agreements will potentially provide for wider population coverage. We will provide an update once the status of the further APAs are known, and once we have had direct conversations with Pfizer regarding their communications processes.

Next steps

64. Subject to your agreement to commit to the binding term sheet with Pfizer, and the Minister of Finance's agreement to the indemnity, the Director General of Health will execute the binding term sheet on behalf of New Zealand.

65. Following the execution of the binding term sheet we will conduct the negotiation on the Definitive Agreement with Pfizer. Once those terms are agreed we will seek your agreement to them and to the drawdown 9(2)(ba)(i), 9(2)(ba)(ii).

66. We will report to you over the next few weeks on the outcomes of negotiations for other APAS as they reach completion, and the overall balance and assessment of the portfolio of COVID-19 vaccines.

Annexes

Annex One: Proposed binding term sheet from Pfizer Inc.

Annex Two: Summary of vaccine purchase framework.

Annex Three: Summary of vaccine purchase framework analysis.

Annex Four: Summary of comparison of binding terms to negotiation priorities.

Annex One: Binding term sheet

Annex Two: Vaccine purchase decision making framework

Ideal set of information for decision making:

1. Vaccine performance	Importance
• Safety profile	CRITICAL
• Effectiveness	CRITICAL
• Ease of distribution across population as a whole or for particular population/ age groups especially Maori	HIGH
• Immunity type: sterilising vs immunity from disease	MED
2. Availability and access	
• Production ○ Confidence in company (eg historic performance) ○ Reliability of supply chains for raw materials ○ Capacity (incl domestic manufacturing and flexibility) ○ Licensing arrangements ○ Delivery schedules	CRITICAL
• Price	HIGH
• Contracting ○ Type of purchasing agreement (eg future buy options) ○ Type of partnership incl with other countries ○ Options to manufacture	HIGH
• 6(a) [redacted]	
• COVAX commitments	

What we can assess in absence of full information from clinical trials:

1. Vaccine performance	Importance
• Available data on safety and effectiveness (likely to be limited to preliminary or final results from Phases I/II) [Note: We are highly unlikely to enter into an APA with no indication of safety and effectiveness]	VERY HIGH
• Safety and effectiveness projections of international experts	VERY HIGH
• Existing APAs by like-minded countries	VERY HIGH
• Track record and reputation of the vaccine developer and key scientists (including signals from regulators and CEPI)	HIGH
2. Availability and access	
• Route to manufacture (arrangements in place; funding; CEPI support)	VERY HIGH

- **Track record, reputation and reliability of manufacturer** **VERY HIGH**
- **Existing APAs by like-minded countries** **VERY HIGH**
- **International risk assessment** **HIGH**
- **Price offered to other countries** **VERY HIGH**

3. Contribution to portfolio balance and strategic approach

To manage risks, the portfolio needs diversity across technology platforms, suppliers, timeframes, and equitable population coverage (including the Pacific). This will become more important over time as the portfolio builds.

Annex Three: Summary of vaccine purchase framework analysis

Application of vaccine purchase decision making framework to the Pfizer Binding Term Sheet and comment from independent experts

Purpose

This document captures information from negotiations, publicly available sources, advice from experts, and confidential information from trusted sources to apply the vaccine purchase framework to the draft purchase arrangement negotiated with Pfizer Inc. Meeting the criteria in the framework informs the decision to enter a Definitive Agreement with the supplier to purchase their vaccine candidate. As well as being one of the priority vaccine candidates, the framework criteria are vaccine performance, availability and access, and contribution to portfolio balance.

Process

Vaccine candidates have been prioritised and Pfizer's candidate is ranked within the top five prospects for an APA (Advance Purchase Agreement). It has also been judged as a suitable contributor in the construction of a portfolio of vaccine candidates for New Zealand. APA negotiations (discussion of binding terms) have concluded. The next step will be for Ministers to make a decision whether to enter an APA with Pfizer.

Overall assessment

The candidate vaccine and the supplier meet the framework criteria of being a priority inclusion in the vaccine candidate portfolio. There is high confidence in the ability of the supplier to deliver a product that meets required quality standards, and while only preliminary information is available, current information on safety and efficacy shows that the vaccine is promising and developing in line with expected performance norms. Other like-minded countries have entered into APAs with the candidate, and there appears to be little international risk for supply of the vaccine (subject to development risk). Issues to be worked through include obtaining resources (infrastructure, consumables and workforce development) needed to support the storage and delivery of the vaccine candidate, and obtaining updated clinical trial information. Fixed delivery obligations to supply cannot be achieved as vaccines are not yet registered and trials are ongoing. Indicative delivery schedules have been agreed. In terms of portfolio mix, the candidate appears to be part of the first group that could be available in New Zealand and obtain regulatory approval in New Zealand. It is an mRNA vaccine, potentially providing cover for around 20% of the adult population. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted]

Key to achievement of framework criteria:

- ✓✓✓ Criteria achieved with confidence, based on current information
- ✓✓ Based on the available information, nothing to indicate that criteria will not be met
- ✓ Criteria could be achieved, but there are issues to be resolved
- × Criteria is not achieved, or will not be achieved
- • No indicators available at the time decisions are made

Supplier - Pfizer			Vaccine name: BNT162
Platform and description			RNA platform – nucleic acid RNZ packaged within a vector (3tNP-mRNAs)
	Importance	Meet framework criteria	
Priority candidate groups; A, B, C	Should be in Group A	Group A ✓✓✓	***The vaccine is highly ranked within priority Group A.*** • Pfizer has very strong track record in producing human vaccines for global use, e.g. for pneumococcal and meningococcal infection. • Pfizer is one of the world's largest pharmaceutical companies, headquartered in New York, USA. • Pfizer and BioNTech have a science-to-vaccine capability, with strengths in speed and scale.
Confidence in priority ranking • This is a multistep process (portfolio selection, science evaluation, international practice and independent validation).	High	✓✓✓	***High confidence in ranking, but some questions are being resolved about the resources needed to deliver the vaccine.*** The science comment (attached as annex 1) is that there is some promise but effectiveness will not be known until Phase II/III trails are concluded. There is high confidence in the supplier's ability to develop, manufacture and deliver a vaccine.

			The comments do not appear to warrant increasing the confidence in the ranking at this stage.
Vaccine performance			*What we can assess in absence of full information from trials*
Safety profile: • Aggregate and non-aggregate (taking into account population groups) • Side effects and adverse reactions	Critical	✓✓	***APAs have been concluded with 'like-minded' countries.*** The following is a list of APSs concluded with 'like-minded' countries, and the number of doses to be provided: US 100m, UK 30m, Canada, discussion with EU. Australia is likely to be in negotiation, no information from Singapore. Also concluded APA with Japan for 120m doses, and more recently with Peru and Chile. Comparator countries have used similar frameworks to ours, using their experts to interrogate the early science results, trial designs and manufacturing programs. The 'top list' of countries for similar safety requirements are: • Australia, Europe (centralised process), MHRA (UK), FDA (US), Canada, SwissMedic. Singapore is also comparable in terms of benefit risk assessment. After AZ, Pfizer has the most APAs with similar countries. ***Other countries' assessments of safety and effectiveness are likely to be the same as ours for the moment.*** • From discussion with other jurisdictions there is a general level of comfort that the supplier is providing consistent information to purchasing parties. There is probably not going to be much more to be learned at this stage. ***Science review panel commentary does not raise undue safety concerns.*** The Panel confirmed that there are currently no licensed vaccines using mRNA technology, so this is an untested platform. The candidate is in the process of Phase II/III trials so it is not possible at this stage to comment on its safety in relation to New Zealand population groups. The science review panel's advice is based only on information available to date, with more information sought from the supplier when

it becomes available. The Panel has concluded that while there are inherent risks with the development of any new vaccine, as well as risks in relation to the new (RNZ) technology platform used, there are not likely to be particular issues with trial design in terms of safety (other than relatively short follow up periods observed in all COVID-19 vaccine trials to date). By the time a decision is expected to be taken in New Zealand whether or not to use it, vaccine additional data are likely to be available from other countries.

Results from Phase I and II https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-share-positive-early-data-lead-mrna

- Germany (NCT04380701): I/II. 456. 18-55 year olds. 56-85 year olds.
- USA (NCT04368728): I/II/II. 18-85 year olds. At least 6000 in Phase II/III
- China (ChiCTR2000034825): 144. 18-55, 55+.

The developer started Phase II/III trials in July 2020:

- aiming for regulatory approval in the 4th quarter 2020
- trials on 18-85 year range (in US, Argentina and Brazil). Participants include both naïve and exposed people
- there is expected to be a staged approach to the release of Phase II/III information, but information will not be available in time for decisions whether to enter into an APA
- the panel noted the post-marketing safety surveillance strategy intended by the developer is not yet clear.

Manufacturing quality/safety will likely be met

- Pfizer is a high reputation global pharmaceutical company so is unlikely to have regulatory approval issues for manufacturing sites. US manufacturing sites would be FDA certified, EU sites would be EMA certified.
- Given the global approach taken by the supplier it is safe to assume that regulatory approval will be sought in a large number of jurisdictions, and definitely in the countries which have an APA already (US, UK, Canada, Japan).
- The timing of information expected to be available for Medsafe is comparable to what is expected for other jurisdictions.

Effectiveness • Aggregate and non-aggregate	Critical	✓✓	***APAs have been concluded with 'like-minded' countries, and other countries' assessment of effectiveness is likely to be the same as ours at this time (see discussion above).*** The 'top list' of countries for efficacy and effectiveness are: • Australia, Europe (centralised process), MHRA (UK), FDA (US), Canada, SwissMedic. Singapore is also comparable in terms of benefit risk assessment. • There is ongoing discussion about whether the disease impact in some of these countries may mean they would approve vaccines with lower levels of effectiveness than New Zealand would – e.g. the US. Comparator countries have used similar frameworks to ours, using their experts to interrogate the early science results, trial designs and manufacturing programs. ***Science review panel concluded that Phase I/II trials show promise*** The scientific panel concluded that, from the data presented by the supplier from Phase I/II trials, the results show some promise, with a comparatively strong immune response (antibody production and T cell response) to vaccination observed. They noted that, as expected, the immune response was dose-dependent and reduced in older people. Efficacy results are expected by the end of October. Of particular note: • This immune response is dose-dependent as expected, but is also reduced in older people (55-85yo) compared to younger adults (18-55 yo). A dampened immune response in older populations is not unusual for vaccines in general. • The vaccine has moved into 2/3 efficacy trials in July 2020, with intended recruitment of 30,000 18-85yo adults in USA, Argentina, Brazil, Germany, South Africa, and Turkey. • It was not clear whether disease severity outcomes (e.g. hospitalisation, death) would also be assessed. It was also not clear if vaccine efficacy for high risk groups (those at risk of severe COVID-19 illness e.g. smokers or people with obesity or lung disease) would be assessed as part of this trial. • More information will become available as trials progress. Highly unlikely to get information on impact on different population groups, although it is requested.

Ease of distribution:	High	✓	***The presentation and format of the vaccine candidate will mean additional resources will be needed to deploy the vaccine and that it may not be suitable for wide-scale application in New Zealand. The requirements to store and dispense the vaccine candidate are being resolved by the Ministry of Health.*** Application • 2-dose regimen in a non-preserved multi-dose vial configuration; first dose, followed by second dose 28 days later, both require intra muscular delivery. Issues to be resolved in terms of suitability for a mass vaccination campaign due to the following challenges: • unfamiliar technology and little experience in administering this type of vaccine • need for second dose, and the precise timing of the second dose[1] • storage and delivery of RNA vaccines due to the need for ultra-cold chain distribution[2] • whether the expected 'presentation' would be suitable for delivery in the New Zealand context, with multi-dose vials[3] (reconstituting vials/doses creates complexity and waste, but these are more efficient for production) • relatively small number of courses available over the first year, 750,000 courses • population groups in which the vaccine has been tested (wide adult age groups in Phase III trials, but no information on other population groups). ***Application may be best for targeted group.*** May be more suitable for a small targeted at-risk population where inoculation could be done in a controlled environment, where it is possible to apply the timing and dose requirements (like a work place). ***Specialised infrastructure and training will be needed to administer this vaccine.***

[1] This is likely to be the case for most COVID-19 vaccines.

[2] Needs to be kept at -70 degrees Celsius (can be kept for 10 days in shipper and then for 15 days with three dry ice top ups). Can be kept frozen for 6 months.

[3] The vaccine will be in a multidose vial containing 5 doses, packed in trays ("pizza boxes"). Each shipper contains 1-5 trays, with shippers being cold chain rated for 10 days at -70°C +/- 10°C. This can be extended by topping up with dry ice. There are 195 vials per tray, 5 trays (975 vials) per bundle i.e. 4875 doses per shipper. Ongoing stability at 2-8°C is 2 days. Needs to be thawed in 2-8 degrees for 30 minutes, diluted and administered at room temp within 6 hours of thawing. It would have a 6 month shelf life. The vaccine is viable at room temperature for up to 6 hours.

			Resources will be needed to manage, distribute and clinically administer this type of vaccine. To note: 9(2)(ba)(i), 9(2)(ba)(ii) Clinical equipment needed for inoculation (other than the ultra-cold storage) is not unusual.[4] Will need to train workforce in both logistics and clinical settings • new techniques create more room for error. Reasons for orange status: risks around administrability • risks from difficulties in administering this type of vaccine • risk from difficulties in administering this type of vaccine in the context of administering a number of vaccines (including other RNA vaccines) which have different requirements • will be impacted by delivery schedule of vaccine portfolio • may be able to mitigate these risks, using-work-arounds such as through geographic restrictions, which may also risks around public perceptions.
Availability and access			
Production: • Confidence in developer • Reliability of supply chains for raw materials • Capacity (including domestic	Critical	✓✓	***High confidence in the quality and ability to supply.*** Scientific panel concluded that the two companies have functions in place to deliver a vaccine; discovery, clinical development, regulatory approval, global manufacture, and established supply chains. Supplier has excellent track record and knowledge of New Zealand market.

[4] Saline dilutent injected into presentation vial with a 21 gauge needle, 5 x 0.3ml dosing syringes, alcohol swabs, protective clothing. Fridges to thaw and store vaccines.

manufacturing and flexibility) • Delivery schedules • Technology platform • Licensing arrangements			***It does not appear that the supplier is selling above their capacity to deliver.*** • The supplier has good manufacturing capacity across Europe and the US • 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] • 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] Have said that they have gone it alone without external funding[5]. Current capabilities and capital of supplier should enable development and scale up of manufacturing capabilities. The technology allows large scale production. • Proposed delivery schedule has moveable start dates to change depending on timing of regulatory approval. • Delivery estimate of Q1 2021 is optimistic (ideal regulatory processes), but this is the norm amongst potential suppliers. • production is expected to be done by the supplier so there is reduced manufacturing risk. • 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] It does not appear that there is a strong risk of the supplier overselling. • In the event that there is an under-supply, no country will get preferential treatment. • Supplier probably has an internal framework, which may prioritise countries with emergency needs, but do not see NZ's supply as being vulnerable (despite relatively smaller demand) ***No contraindications on reliability of supply chains*** • Supplier has selected production centres to minimise production risks, but no guarantees are possible. ***Delivery schedule is not certain***

[5] But some indication of operation warpseed funding and German government funding.

			• Fixed delivery obligations to supply cannot be achieved as trails are still ongoing and vaccines cannot be registered. • 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] • While we should plan for delivery in the first quarter, we should be prepared for delays by at least one quarter. • Date of supply depends on regulatory approval, Pfizer has commenced engagement with Medsafe, and informed of need to satisfy EPA requirements. Pfizer has started to meet Medsafe for regulatory pre-submission meetings in late September with a view to filing an application in December 2020. ***Technology platform is novel.*** Nucleic acids are a less well established technology platform, and have not been used to produce human vaccines at scale to date, so will require additional information for regulatory approval. ***Pfizer has ruled out local licensing to manufacture the vaccine in New Zealand.***
Contracting: • Type of purchasing agreement • Partnership with other countries • Options to manufacture • COVAX implications	High	✓✓✓	***Type of purchase agreement*** 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] [redacted] ***Purchase is from manufacturer so no partnership with other countries.***

[6] 300k doses estimated to be shipped in Q1 of 2021, 400k doses estimated to be shipped in each subsequent Q of 2021.

			Though there may be risk of export controls and the vaccine would be stopped at the border). ***Pfizer have indicated that they are negotiating an arrangement with COVAX.*** • Pfizer indicated that there is complexity for manufacturers from how COVAX's supply chains may work. • Because Pfizer hasn't completed deals with COVAX, the supplier is not in a position to confirm, but it is their intent that they will) ○ other vaccines with more standard storage and distribution will be more suitable for GAVI.

International risk assessment:
• Health, economic and social impacts of pandemic (impacts on demand and availability)
• State support for development and manufacturing
• Sovereign hoarding
• US election
• COVAX commitments
	High	Low
		✓✓✓
			COVID-19 continues to cause a global health crisis, the worldwide demand for vaccines is still high, and production is heavily constrained.
			
			Firm risk is low
			• Headquartered in New York, global footprint, manufacturing in a number of locations.
			• Manufacture will be in US and EU with separate supply chains, believe supply would come from EU, but supply site decisions are reserved by supplier.
			• Strong collaboration and track record[7]; BIoNTech (Germany), Pfizer (US), with parallel collaboration in China with Fosun Pharmaceutical (China).
			
			State support for development and manufacturing is ambiguous
			• Funded US $1.95 billion as part of Operation Warpspeed
			  ○ Hasn't been mentioned in meetings, may be specific to US agreements.
			• EURO 300 million from German government
			  ○ Pfizer has said it has not sought external funding and has gone it alone – verified in meeting.
			
			US and sovereign hoarding risks are low.

[7] Collaboration by BioNTech and Fosun Pharmaceutical to develop BNT162 as a vaccine for use in China. Subsequent agreement with Pfizer to co-develop and distribute for the rest of the world. Leverages BioNTech's proprietary mRNA platforms for infectious diseases. Research undertaken in facilities in the US and Germany operated by both companies. Jointly developed an mRNA-based influenza vaccine in 2018. Leveraging Pfizer's commercial and regulatory capabilities

			• 6(a) [redacted] ***Latest version of COVAX commitments are unlikely to conflict with bilateral arrangements.*** Unsure of supply to COVAX, and any priority rights.
Number of doses			***1.5 million doses, should cover 20% of the New Zealand adult population.*** Supplier has used World Bank numbers to determine New Zealand's supply.
Cost		✓✓✓	9(2)(ba)(i), 9(2)(ba)(ii) [redacted]
Contribution to portfolio balance			
Diversity of vaccine platforms		✓✓✓	mRNA vaccine. 9(2)(ba)(i), 9(2)(ba)(ii) [redacted] Not purchasing Pfizer vaccine may mean that two important components of the portfolio may be missing (from candidates in the target group approved by the Taskforce): • early delivery • RNA vaccine.

Diversity of suppliers		✓✓✓	Likely to be manufactured in EU by Pfizer. Not CEPI funded[8]. In discussion with COVAX (see above).
Sufficient coverage, without risk of over-purchase		✓✓✓	***1.5 million, so will cover around 20% cover of New Zealand adult population, but there is no information about application to particular population groups.*** • highly unlikely to get information on impact on different population groups, although it is requested • trials cover a wide age range, from 18 to 85 yo.
Early access/Delivery timeframes		✓✓	***Is likely to be one part of the earliest group of vaccines to become available.*** • terms suggest supply to be available from 1st quarter 2021 to 3rd quarter 2021 , but there is no commitment to supply to that schedule • Medsafe consider later than first quarter in 2021 is more realistic • it would be pragmatic to manage expectation of delivery to 2nd quarter, but be prepared for it to arrive in 1st quarter. • can assume that all producers in the earliest group are probably being optimistic, and a delay of a quarter can be expected for most suppliers. Don't want to put pressure on providers to rush approval (if this means cutting corners) • Medsafe is working on a regulatory processes to be able to deal with concurrent applications. We understand Medsafe will use an abbreviated evaluation process (AEP) and draw on assessments undertaken by authorities recognised under the AEP.

[8] https://cepi.net/research_dev/our-portfolio/

Other matters not part of the framework analysis		
Suitability for different population groups	◆	Unlikely to be able to determine this at the time decisions are made.
Duration of immunity	◆	Unlikely to be able to determine this at the time decisions are made.
Immunity type	◆	Sterilising immunity, but this is likely to be a continuum and will depend upon the time point at which it is measured. While some vaccines may achieve sterilising immunity early, it is likely this will fade with time. In the long run, most vaccines are likely to protect against disease but not infection[9].
Multi-lateral or bilateral		Bilateral
APAs concluded by New Zealand		No other APAs have been concluded.

2 October 2020

[9] Comment from STAG.

Pfizer COVID-19 candidate vaccine

2nd September 2020

Pfizer presented their candidate mRNA vaccine (BNT162b2) to the Science Review Panel on 1st Sept 2020. There are currently no licenced vaccines using mRNA technology, so this is an untested platform. However, the data presented by Pfizer from Phase I/II trials are promising, with an immune response (antibody production and T cell response) to vaccination observed. This immune response is dose-dependent as expected, but is also reduced in older people (55-85yo) compared to younger adults (18-55 yo). A dampened immune response in older populations is not unusual for vaccines in general. Reactogenicity (e.g. injection site swelling, post-vaccination fever) of this vaccine is also within the expected range.

This vaccine moved forward in to Phase II/III efficacy trials in July 2020, with intended recruitment of 30,000 18-85yo adults in USA, Argentina, Brazil, Germany, South Africa, and Turkey. The trial will assess how effective the vaccine is at preventing new diagnoses of COVID-19, both in those with and without evidence of prior COVID-19 infection. It was not clear whether disease severity outcomes (e.g. hospitalisation, death) would also be assessed. It was also not clear if vaccine efficacy for high risk groups (those at risk of severe COVID-19 illness e.g. smokers or people with obesity or lung disease) would be assessed as part of this trial. We have requested further clarifications from Pfizer about these details as well as the long term safety and immunogenicity follow-up intended for participants in this trial. The developer is aiming for regulatory approval in the fourth quarter of 2020 and the post-marketing safety surveillance strategy intended by the developer is not yet clear.

This vaccine is being tested as a 2-dose vaccine, and is presented frozen, in multi-dose vials (5 doses per vial, which must be used within a few hours of opening or discarded). Current vaccine delivery mechanisms in New Zealand cater for vaccines stored at 2-4°C rather than frozen, and adaptations to vaccine delivery systems would need to be made to accommodate this vaccine. Such adaptations might be easier to implement if vaccination were conducted at selected key clinics rather than all vaccine providers. It is currently not clear if a single dose schedule for this vaccine has, or will be, investigated.

It appears that vaccine doses can be manufactured at speed once licensed, because required doses are small and because the developers have functions in place to deliver including global manufacturing and supply chains. However, it is not clear if Pfizer has intentions to license vaccine production to other manufacturers, which would allow the possibility of production in New Zealand.

Annex Four: Comparison of binding term sheet with negotiation priorities

MINISTRY OF HEALTH
MANATŪ HAUORA

MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

BRIEFING

Supply agreement for purchase of COVID-19 vaccines from Pfizer New Zealand Ltd.

Date:	18 December 2020	**Priority:**	Urgent
Security classification:	Sensitive	**Tracking number:**	2021-1847

Purpose

To seek approval for the Director General of Health to execute a definitive supply agreement for the, already agreed and announced, purchase of vaccines against COVID-19 from Pfizer New Zealand Ltd[1]. We also seek agreement appropriate funds for the purchase.

Executive summary

Background

Ministers agreed in early October to a binding heads of terms agreeing to an offer from Pfizer Inc. (Pfizer) for the purchase of 750,000 courses of an mRNA vaccine candidate for delivery early next year (briefing MBIE 2021-0996 refers). In November Joint Ministers also agreed to non-binding heads of terms with Janssen Pharmaceutica NV (Janssen) for the purchase of five million courses of a viral vector vaccine for delivery in 9(2)(ba)(i) & (ii) (briefing MBIE 2021-1195 refers). Both these arrangements require the negotiation and execution of definitive supply agreements. In parallel with this briefing we have provided advice on the conclusion of a definitive supply agreement with Janssen (briefing MBIE 2021-1849 refers).

Earlier this month Joint Ministers agreed to binding supply agreements with AstraZeneca Ltd. for the delivery of 3.8 million courses of a viral vector vaccine (briefing MBIE 2021-1537 refers) and with Novavax Inc. for the purchase of 5.36 million courses of a protein sub-unit vaccine (briefing MBIE 2021-1723 refers), 9(2)(ba)(i) & (ii)

New Zealand announced a binding agreement with Pfizer for the purchase of Pfizer's vaccine candidate on 12 October this year. The purchase was negotiated as a binding heads of terms, to be followed by a definitive agreement that would include detail and other supply matters. On 5 October the Minister of Finance granted an indemnity in favour of Pfizer and BioNTech conditional on and commencing at the execution of a definitive supply agreement by all parties.

We recommend that you agree that the proposed definitive supply agreement with Pfizer Inc. should be concluded

The execution of a definitive supply agreement without delay is important to provide certainty and lead in time for Pfizer to plan the manufacture of vaccines for New Zealand, and for the Ministry of Health to plan for administering those vaccines.

The definitive supply agreement has been negotiated with the advice of legal and commercial experts. An interagency approach (including PHARMAC) was taken in the negotiations and an appropriate outcome has been achieved. We seek your agreement to execute the proposed definitive supply agreement and to appropriate 9(2)(ba)(i) & (ii) million to fund the purchase of the vaccines.

[1] The contracting party to the binding heads of terms agreement was Pfizer Inc. and the contracting party to the proposed definitive agreement is Pfizer New Zealand Ltd. For simplicity, both are referred to as "Pfizer" in this briefing.

The substantive terms of the proposed supply agreement were agreed in the binding heads of terms agreement with Pfizer. A number of general supply terms, commonly found in agreements for the purchase of medicines, such as product specifications and processes to be used to order and take delivery of the vaccines, are included in the supply agreement. Annex Two outlines noteworthy additional terms for the proposed purchase agreement, the main ones include:

- 9(2)(ba)(i) & (ii)
-
-
- due to packaging sizes, the actual volumes purchased by New Zealand will be 750,260 (an additional 260 courses of the vaccine) raising the total purchase cost by 9(2)(ba)(i) & (ii)

The supply agreement includes an indemnity provision that is in substance the same as the deed of indemnity granted by the Minister of Finance on 5 October (though Pfizer has made minor changes to the wording). The Minister of Finance is required to approve the indemnity provisions in the definitive supply agreement and to sign the supply agreement as a contracting party in respect of those indemnity provisions. Treasury officials will advise the Minister of Finance on the indemnity provisions in the proposed definitive supply agreement.

In November, Pfizer announced that the efficacy of their candidate is 95 percent. The vaccine has been authorised for emergency use in several countries including in the United Kingdom, Canada, Singapore and the United States. Interim data from phase III trials have been published recently and show that the vaccine's efficacy rate of 95 percent is consistent across all population subgroups and the reactogenicity results are broadly similar to earlier phase I/II trials.

Next steps

Subject to your agreement to the recommendations in this briefing, the Director-General of Health on behalf of the New Zealand Government, will sign the proposed definitive supply agreement (attached at Annex One). The Minister of Finance will be required to approve the indemnity provisions in the definitive supply agreement and to sign the supply agreement in respect of those provisions.

Given that the arrangement with Pfizer was announced as a confirmed purchase in October we do not recommend a further announcement about the execution of the definitive supply agreement.

Recommended action

The Ministry of Business, Innovation and Employment, and the Ministry of Health recommend that you:

a) **Note** the information in this briefing is subject to confidential disclosure agreements with vaccine developers and should be treated as commercially sensitive.

Noted

b) **Note** an unprecedented global health crisis continues and the New Zealand population remains almost totally susceptible to COVID-19 due to our successful elimination strategy.

Noted

c) **Note** in May Cabinet approved the COVID-19 Vaccine Strategy [CAB-20-MIN-0229.01] with the objective of ensuring access to a safe and effective vaccine to implement the Government's preferred immunisation strategy at the earliest possible time.

Noted

d) **Note** in early October Ministers agreed to the terms of a binding heads of terms arrangement with Pfizer Inc. for the purchase of 750,000 courses of an mRNA vaccine candidate for delivery early next year (briefing MBIE 2021-0996 refers). The Minister of Finance provided an indemnity to Pfizer Inc. and BioNTech (and others) pursuant to the agreement and tabled a statement to the House on 27 November. The binding agreement was announced on 12 October and requires parties to conclude a definitive supply agreement.

Noted

e) **Note** in mid-November Ministers agreed to a non-binding heads of terms agreement with Janssen Pharmaceutica NV for the purchase of five million courses of a viral vector vaccine for delivery in 9(2)(ba)(i) & (ii) (briefing MBIE 2021-1195 refers). The non-binding heads of terms agreement requires parties to conclude a definitive supply agreement, on which we will advise you separately.

Noted

f) **Note** Ministers have also agreed to enter into a binding supply agreement with AstraZeneca Ltd for the purchase of 3.8 million courses of a viral vector vaccine (briefing MBIE 2021-1537 refers), and with Novavax Inc. for the purchase of 5.36 million courses of a protein sub-unit vaccine (briefing MBIE 2021-1723 refers), 9(2)(ba)(i) & (ii)

Noted

g) **Note** a definitive supply agreement has been negotiated with Pfizer (attached as Annex One). An inter-agency approach (including PHARMAC), has continued for these negotiations. Advice has been taken from legal and commercial experts and appropriate terms have been negotiated.

Noted

h) **Note** the substantive terms of the proposed supply agreement negotiated with Pfizer were agreed in the binding heads of terms arrangement executed in October. The proposed agreement also includes a number of general supply terms, not inconsistent with the binding arrangement and commonly found in agreements for the purchase of medicines, such as product specifications and processes to be used to order and take delivery of the vaccines.

Noted

i) **Note** significant additional terms in the proposed agreement are outlined in Annex Two. They include:

- 9(2)(ba)(i) & (ii)
-
-

- due to packaging requirements New Zealand will be purchasing 260 additional courses of the vaccine (raising the total purchase cost by 9(2)(ba)(i) & (ii)

Noted

j) **Note** The execution of a definitive supply agreement without delay is important to provide certainty and lead in time for Pfizer to plan the manufacture of vaccines for New Zealand, and for the Ministry of Health to plan for administering the vaccine.

Noted

k) **Agree** that the Director General of Health execute the proposed supply agreement for the purchase of 750,260 courses of Pfizer Inc's vaccine on behalf of the New Zealand Government (the terms of the proposed supply agreement are attached in Annex One). Your agreement is subject to the agreement of the Minister of Finance to grant a new indemnity to Pfizer and BioNTech (and others).

Agree / Disagree

l) **Note** Cabinet established a tagged contingency of up to 18(d) million [CAB-20-MIN-382 and CAB-20-MIN-0504] for purposes of purchasing suitable vaccines, including entering into advance purchase agreements to purchase potential COVID-19 vaccines. Cabinet also delegated purchase decisions to the Prime Minister, the Minister of Finance, the Minister of Research, Science and Innovation, the Minister for COVID-19 Response, and the Minister of Health (Joint Ministers).

Noted

m) **Agree**, if you agree to the recommendation in k), to draw down 9(2)(ba)(i) & (ii) million from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' to purchase 750,260 courses of Pfizer Inc.'s vaccine.

Agree / Disagree

n) **Approve**, if you agree to the recommendation m), the following changes to appropriations to provide for that decision, with a corresponding impact on the operating balance and net core Crown debt:

	$m - increase/(decrease)				
Vote Health Minister of Health	**2020/21**	**2021/22**	**2022/23**	**2023/24**	**2024/25 & Outyears**
Non-Departmental Output Expenses: Minimising the Health Impacts of COVID-19	9(2)(ba)(i) & (ii)	-	-	-	-
Total Operating	9(2)(ba)(i) & (ii)	-	-	-	-

Approve/ Not approve

o) **Authorise** the Minister of Finance and the Minister of Health to transfer any unspent 2020/21 funding in Vote Health agreed under the recommendation n) to the 2021/22 financial year, as required, with no impact on the operating balance and net core Crown debt across the forecast period.

Authorised/ Not authorised

p) **Agree** that the changes to appropriations for 2020/21 above be included in the 2020/21 Supplementary Estimates and that, in the interim, the increase be met from Imprest Supply.

Agree / Disagree

q) **Note** that the Minister of Finance will be required to approve the indemnity provisions in the definitive supply agreement and to sign the supply agreement in respect of those provisions. Treasury officials will advise the Minister of Finance on the indemnity provisions in the proposed definitive supply agreement.

Noted

Rt Hon Jacinda Ardern

Prime Minister

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

Hon Grant Robertson

Minister of Finance

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

Hon Dr Megan Woods

Minister of Research, Science, Innovation

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

Hon Chris Hipkins

Minister for COVID-19 Response

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

Hon Andrew Little

Minister of Health

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

Maree Roberts

Deputy Director-General,

Ministry of Health

18 / 12 / 2020

Dr Peter Crabtree

General Manager, Science, Innovation and International, MBIE

18 / 12 / 2020

Background

Global demand for COVID-19 vaccines remains high

1. An unprecedented health crisis continues worldwide, and New Zealand's population remains entirely susceptible to COVID-19 due to our successful elimination strategy.

2. Our ability to recover from the COVID-19 pandemic and relax public health controls relies on the availability of safe and effective COVID-19 vaccines. The global demand for COVID-19 vaccines continues to be high, and capacity to manufacture successful vaccine candidates is heavily constrained worldwide. This constraint is expected to be the case for some time.

Ministers have previously agreed to a COVID-19 vaccine purchasing strategy and a framework to guide purchase decisions

3. In May, Cabinet agreed a purchasing strategy to support acquisition of COVID-19 vaccines [CAB 20-MIN-0382] with the objective of managing a range of risks and providing safe and effective COVID-19 vaccines to implement the Government's preferred immunisation strategy for New Zealand and for use in the Pacific.

4. In August and November, Cabinet set aside a tagged contingency of up to 18(d) million [CAB-20-MIN-382 and CAB-20-MIN-0504] in order to finance advance purchase agreements (APAs) of potential COVID-19 vaccines and to meet additional early costs of the Government's immunisation programme. Cabinet also delegated purchase decisions to the Prime Minister, the Minister of Finance, the Minister of Research, Science and Innovation, the Minister for COVID-19 Response, and the Minister of Health (Joint Ministers).

5. 9(2)(ba)(i) & (ii)

   Money spent on APAs will be lost if the development is unsuccessful, if the candidate is found to be unsuitable for deployment as part of the Government's preferred immunisation strategy, or if the supply is in excess of what is required under that strategy and cannot be on-sold. In the current global context, this is the cost of attempting to secure supply of vaccines that are still being developed.

Ministers have agreed to terms to purchase four COVID-19 vaccine candidates

6. In early October this year, Joint Ministers agreed to the terms of a binding heads of terms arrangement with Pfizer Inc. (Pfizer) for the purchase of 750,000 courses of an mRNA vaccine candidate for delivery early next year (briefing MBIE 2021-0996 refers). The Minister of Finance provided an indemnity to Pfizer and BioNTech (and others) pursuant to the arrangement which was tabled in Parliament on 26 November. The binding arrangement was announced on 12 October. The arrangement requires parties to conclude a definitive supply agreement.

7. In November, Joint Ministers agreed to non-binding heads of terms from Janssen Pharmaceutica NV (Janssen) for the purchase of five million courses of a viral vector vaccine 9(2)(ba)(i) & (ii) (briefing MBIE 2021-1195 refers). The non-binding agreement was announced on 19 November, and requires parties to conclude a definitive supply agreement. In parallel with this briefing we have provided advice on the conclusion of a definitive supply agreement with Janssen (briefing MBIE 2021-1849 refers).

8. Earlier this month, Joint Ministers have agreed to enter into a binding supply agreement with AstraZeneca Ltd for the purchase of 3.8 million courses of a viral vector vaccine (briefing MBIE 2021-1537 refers), and with Novavax Inc. for the purchase of 5.36 million courses of a protein sub-unit vaccine (briefing MBIE 2021-1723 refers), 9(2)(ba)(i) & (ii)

Concluding the definitive supply agreement with Pfizer is critical to the timely roll-out of the vaccine

9. Considerable planning is required to administer the Pfizer vaccine because of the requirement that the vaccine be stored at -70 degrees Celsius, new clinical process required to administer the vaccine, and because it could potentially be the first COVID-19 vaccine to be administered in New Zealand. Conclusion of the proposed supply agreement will provide certainty and lead in time for the Ministry of Health to undertake that planning.

10. Pfizer have indicated that significant planning is required to manufacture and deliver the vaccine, 9(2)(ba)(i) & (ii)

11. To enable these processes to proceed in a timely manner a definitive purchase arrangement with Pfizer should be concluded without delay.

12. 9(2)(ba)(i) & (ii)

A proposed supply agreement in line with the binding terms previously agreed with Pfizer have been negotiated

13. We have negotiated a proposed definitive supply agreement with Pfizer (attached as Annex One). An inter-agency approach, including PHARMAC, has continued to be taken in negotiations. We have taken legal and commercial advice from Bell Gully and others during the negotiation.

14. We consider that appropriate terms for the purchase of potential COVID-19 vaccines have been negotiated with Pfizer. The substantive terms of the proposed definitive supply agreement were negotiated in the binding heads of terms arrangement and have been maintained, 9(2)(ba)(i) & (ii)

15. A number of general supply terms not inconsistent with the binding heads of agreement, commonly found in agreements for the purchase of medicines, such as product specifications, manufacturing and quality standards, and processes to be used to order, take delivery and administer the vaccines are included in the proposed supply agreement. Noteworthy changes are discussed in Annex Two. They include:

    - 9(2)(ba)(i) & (ii)
    - due to packaging requirements New Zealand will be purchasing 260 additional courses of the vaccine (raising the total purchase cost by 9(2)(ba)(i) & (ii)

A new indemnity on substantially the same terms as that agreed for the binding heads of terms agreement is required from the Crown

16. The supply agreement includes an indemnity provision that is in substance the same as the deed of indemnity that the Minister of Finance granted on 5 October (though Pfizer has made minor changes to the wording).

17. Due to the way the documents are drafted, both the original deed of indemnity and the indemnity provisions in the definitive supply agreement will be in force once the Minister of Finance signs the definitive supply agreement.

18. Taking advice from Bell Gully we have decided to resolve this issue by revoking the original indemnity after the definitive supply agreement is executed. The result will be that only the indemnity in the definitive supply agreement will remain in force. Pfizer have not expressed any concerns with this approach.

19. The alternative would have been to seek to include a provision to the effect that the indemnity in the proposed definitive supply agreement supersedes the deed of indemnity. This would have risked prolonging negotiations with Pfizer.

20. Treasury officials will advise the Minister of Finance on the indemnity provisions in the proposed definitive supply agreement. The Minister of Finance is required to approve the indemnity provisions in the definitive supply agreement and to sign the definitive supply agreement as a contracting party in respect of those provisions.

We recommend that the proposed definitive supply agreement is concluded without delay

21. We recommend that you agree that the Director General of Health execute the proposed supply agreement for the purchase of 750,260 courses of Pfizer's vaccine on behalf of the New Zealand Government (the terms of the proposed supply agreement are attached in Annex One). Your agreement that the Director General execute the definitive supply agreement is subject to the Minister of Finance's agreement to grant a new indemnity to Pfizer and BioNTech.

Securing additional COVID-19 vaccines for our portfolio

22. 9(2)(ba)(i) & (ii) [redacted] We consider that the 'core portfolio' lacks sufficient broad coverage without the additional Pfizer doses and will therefore continue to seek additional courses of the vaccine from Pfizer and through the COVAX Facility. We will also investigate the purchase of another high-volume candidate and continue to consider smaller purchases, including through the COVAX Facility.

Recent results and media statements about the Pfizer vaccine

23. Since the binding heads of terms agreement was executed in October the vaccine has been authorised for emergency use in several countries including in the United Kingdom, Canada, Singapore and the United States. Also, Pfizer announced in November that their vaccine is 95 percent effective. We should be cautious about drawing conclusions about the suitability of vaccines for our preferred portfolio from statements made by suppliers because:

- the statements are media messages rather than clinical data about the safety and efficacy of the candidates and there is little that can be concluded other than there appears to be some efficacy

- the claims of efficacy are not directly comparable between the candidates
- regulators will need to view data to assess efficacy and safety, including to enable comparisons to be made between the candidates.

24. Some results from phase III trials have also been published this month. The vaccine has an efficacy rate of 95 percent seven days after the second dose has been administered, and this rate was consistent across all population subgroups. The reactogenicity results are broadly similar to earlier phase I/II trials. There were two deaths in the trial group, however these were considered by the investigators to be unrelated to the vaccine.

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

25. If you agree that the proposed definitive supply agreement should be executed, a draw-down of 9(2)(ba)(i) & (ii) million from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency' will be required to fund the purchase price for 750,260 courses of Pfizer's vaccine candidate. 9(2)(ba)(i) & (ii)

26. The draw-down would enable the following payments to be made:

Payment	Timing	Cost (NZ$)
9(2)(ba)(i) & (ii)		
Total		9(2)(ba)(i) & (ii)

* 9(2)(ba)(i) & (ii)

27. Delivery schedules are not certain and there is possibility that deliveries could be delayed or brought forward. To manage this uncertainty we recommend that the funds for purchase be appropriated to the current financial year and you authorise the Minister of Finance and the Minister of Health to transfer any unspent 2020/21 funding to the 2021/22 financial year.

Communications and publicity

28. Given that the arrangement with Pfizer was announced as a confirmed purchase in October we do not recommend a further announcement about the execution of the definitive supply agreement.

Next steps

29. Subject to your agreement to the execution of the proposed definitive supply agreement, and the Minister of Finance's agreement to be a counterparty in respect of the indemnity provisions in the agreement, the Director-General of Health will sign the definitive supply agreement with Pfizer on behalf of the New Zealand Government. The Minister of Finance will also sign as a counterparty in relation to the indemnity provisions in the agreement.

30. 9(2)(ba)(i) & (ii)

31. We will provide separate advice on the conclusion of negotiations for a definitive supply agreement with Janssen.

Annexes

Annex One: Proposed definitive supply agreement with Pfizer Inc.

Annex Two: Summary of notable new provisions in the proposed definitive supply agreement.

BRIEFING

COVID-19 Vaccine Strategy – Additional bilateral Pfizer purchase

Date:	10 February 2021	**Priority:**	High
Security classification:	Sensitive	**Tracking number:**	MBIE: 2021-2236

Action sought		
	Action sought	**Deadline**
Rt Hon Jacinda Ardern **Prime Minister** Hon Grant Robertson **Minister of Finance** Hon Dr Megan Woods **Minister of Research, Science and Innovation** Hon Chris Hipkins **Minister for COVID-19 Response** Hon Andrew Little **Minister of Health**	**Agree** to purchase additional quantities of Pfizer's vaccine candidate.	12 February 2021
Hon Nanaia Mahuta **Minister of Foreign Affairs** Hon Dr Ayesha Verrall **Associate Minister of Health and RSI**	**Note** the contents of this briefing for your information.	

Contact for telephone discussion (if required)			
Name	**Position**	**Telephone**	**1st contact**
Simon Rae	Manager, COVID-19 Vaccine Policy and Strategy, MBIE	9(2)(a)	✓
Maree Roberts	Deputy Director-General, System Strategy and Policy, MOH	9(2)(a)	
Zachary Clarke	Policy Advisor, MBIE	9(2)(a)	

The following departments/agencies have been consulted
MBIE, MFAT, MOH, Treasury

Minister's office to complete:

- ☐ Approved
- ☐ Noted
- ☐ Seen
- ☐ See Minister's Notes
- ☐ Declined
- ☐ Needs change
- ☒ Overtaken by Events
- ☐ Withdrawn

Comments

BRIEFING

COVID-19 Vaccine Strategy – Additional bilateral Pfizer purchase

Date:	10 February 2021	**Priority:**	High
Security classification:	Sensitive	**Tracking number:**	MBIE: 2021-21236

Purpose

To seek your approval to negotiate with Pfizer to purchase additional doses of its COVID-19 vaccine candidate. We recommend purchasing fewer than the full 8 million courses offered, and have suggested two alternative purchase volumes in this briefing.

Recommended action

The Ministry of Business, Innovation and Employment (MBIE) and the Ministry of Health recommend that you:

1. **Note** that Pfizer has offered us 8 million additional doses (sufficient for 4 million people) of its COVID-19 vaccine candidate. Unlike COVAX offers, we are not required to purchase the full amount.

Noted

2. **Note** that this offer is in addition to our existing advanced purchase agreements (APAs) with Pfizer for 1.6 million doses (1.5 million bilaterally and 100,620 through COVAX)

Noted

3. **Agree** to purchase additional quantities of Pfizer's vaccine under either Option 1 or Option 2:

    a. Option 1: Purchase **1.5 million** additional courses to fully vaccinate at risk groups (1.55m if COVAX is declined).

Agree / Disagree

    b. Option 2: Purchase **2.56 million** additional courses to provide greater certainty that we will have sufficient vaccines in 2021 (2.61m if COVAX is declined)

Agree / Disagree

4. **Note** that the Ministry of Health does not support Option 2 as it does not consider there to be sufficient public health benefits from purchasing more than an additional 1.5 million courses.

Noted

5. **Agree** that, if you agree to purchase additional doses, officials decline our COVAX purchase option for Pfizer's vaccine, and instead purchase an additional 50,000 courses under the new bilateral agreement.

Agree / Disagree

6. **Note** that the Ministry of Health is considering further options to manage the vaccine portfolio. These may include adjusting delivery schedules, donations for the Pacific, and further purchase opportunities that will need to be considered as additional information evidence becomes available on COVID-19 and the vaccines in our portfolio.

Noted

7. **Note** that, if you agree to purchase additional doses, we will return for Joint Ministers' approval to sign the subsequent purchase agreement, to draw down the necessary funding, and to confirm availability of consumables and freezers.

Noted

Rt Hon Jacinda Ardern
Prime Minister

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

Hon Grant Robertson
Minister of Finance

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

Hon Dr Megan Woods
Minister for Research, Science, Innovation

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

Hon Chris Hipkins
Minister for COVID-19 Response

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

Hon Andrew Little
Minister for Health

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

Maree Roberts	Dr Peter Crabtree
Deputy Director General, System Strategy and Policy, MOH	**General Manager, Science, Innovation and International, MBIE**
10/02/2021	10/02/2021

Background

1. Our Vaccine Strategy seeks to secure sufficient quantities of safe and effective vaccines in order to complete our Immunisation Programme at the earliest possible time. Our current vaccine portfolio consists of the following vaccines:

    - Pfizer 800,310 courses (incl. 50,310 through COVAX)
    - AstraZeneca 4.634 million courses (incl. 834,000 through COVAX)
    - Janssen 5 million courses
    - Novavax 5.36 million courses

2. We originally advised Cabinet in November (CAB-20-SUB-0508 refers) that we needed to purchase four wide population coverage vaccines before our portfolio would be complete. The Ministry of Health defines wide population coverage as 5.36 million courses for both New Zealand and Polynesia, including a significant buffer for wastage.

3. At the time, we were in discussions with Pfizer around purchasing additional quantities of its candidate. Pfizer's vaccine has been a key target for our portfolio due to its high effectiveness and early delivery schedule. While Pfizer ultimately informed us that additional doses were no longer available for purchase in 2020, we have continued discussions with the company to maintain the option of securing additional doses should they become available.

4. Our overall portfolio assessment was made before initial clinical trial data became available for all of our candidates. This data now indicates that, to varying degrees, all four of our portfolio candidates are effective against COVID-19, with few early safety concerns. However, it is currently unclear how effective our portfolio vaccines are against newer variants of COVID-19. This may impact decisions on whether we use particular vaccines in New Zealand, despite otherwise being effective against the original COVID-19 strains.

We have been offered 4 million additional courses of Pfizer's vaccine

5. Pfizer has directly offered us an additional 8 million doses of its two dose mRNA vaccine. The offer includes the following key details:

    - **Volume:** Up to 8 million doses (sufficient for 4 million people)
    - **Price per dose:** 9(2)(ba)(i) & (ii) per course/person)
    - **Total purchase cost:** Up to 9(2)(ba)(i)&(ii) million
    - **Estimated delivery:** Q3-Q4 2021

6. 9(2)(ba)(i) & (ii) [redacted]

Pfizer is the most logistically complex vaccine in our portfolio, and the additional doses pose several challenges

We will only benefit from the additional doses if these can be effectively utilised by the Immunisation Programme

7. The value of additional Pfizer doses is dependent on the Immunisation Programme's ability to administer the logistically complex vaccine. We do not recommend purchasing the full 8 million doses offered as the vaccine's difficult storage requirements are likely to make it unsuitable for delivery and administration outside major population centres.

8. Pfizer's vaccine needs to be stored at -60°C to -90°C before use. The full 8 million doses would exceed the Ministry of Health's ultra-cold storage and logistics arrangements, which can currently hold 1.5 million doses simultaneously. Additional investments may be needed to increase this capacity even if we purchase a reduced number of doses, particularly if the majority of the doses arrive in a single quarter. However, fewer investments would be required we are able to divide the courses across Q3 and Q4.

9. A key constraint is whether we can source sufficient additional and timely quantities of the specialised diluents, drawing needles, and syringes required to administer Pfizer's vaccine. The Ministry of Health will immediately begin investigating potential options to source additional supplies, but high global demand may delay their arrival (particularly for doses scheduled to arrive in Q3 2021).

10. Pfizer's vaccine is likely to take more time to distribute and administer than other portfolio vaccines, particularly as the vaccine can only be used for a short period once it is removed from the freezers and distributed to an immunisation centre. We therefore expect it to have a greater degree of wastage than any other vaccine in our portfolio, and have accounted for this risk in our suggested purchase volumes.

The European Union's vaccine export restrictions may impact our Pfizer deliveries

11. Under our existing APA with Pfizer, doses destined for New Zealand may be manufactured in Belgium (although the place of manufacture is not specified in the contract). There is therefore some risk that the European Commission's existing export restrictions on COVID-19 vaccines, which are intended to run until 31 March 2021, may delay existing orders, be extended for a longer period, 6(a) 6(a) [redacted]

12. 6(a) [redacted]

13. 6(a) [redacted]

6(a) [redacted]

The offer could increase the options available to the Immunisation Programme

14. While we do not recommend purchasing the full 8 million doses, we could strengthen the options available to the Immunisation Programme by purchasing a smaller number of doses. This could enable us to access additional quantities of safe and highly effective vaccines earlier than otherwise possible.

15. There are two primary options we could pursue. We recommend purchasing at least 1.5 million additional courses so that we can fully immunise at-risk groups with just Pfizer's vaccine. We could alternatively purchase 2.56 million courses (an additional 1.06 million courses) to provide greater certainty that we will have sufficient vaccines for the Immunisation Programme in 2021.

Purchase Option 1: Purchase 1.5 million additional courses to fully immunise higher risk population groups

Volume: 3 million doses (1.5 million courses)
Total Cost: 9(2)(ba)(i)&(ii) million

16. Pfizer's overall effectiveness (around 95% effective at preventing symptomatic infection) make it an attractive candidate for use in higher risk groups. Pfizer is one of the most effective vaccines currently available on the market, including for older people for whom vaccines are often less effective. It is notably more effective than initial effectiveness data indicates for AstraZeneca and Janssen's candidates (62% and 72% effective respectively). Initial data indicates that Novavax's candidate is also around 95% effective[1], but we have less information about that candidate's performance in older people and it will deliver later in 2021 and 2022 (Q2 2021 to Q2 2022).

17. Because we have more information about Pfizer's vaccine, we currently have greater confidence about its suitability for use in the Immunisation Programme than our other portfolio vaccines. It has already been widely used across the globe and is the only candidate to achieve Medsafe approval to date, without any significant conditions on its use. While we are reasonably confident that at least some of our other candidates will also receive approval, there is less certainty about whether Medsafe will require any conditions that might prevent them from being used in a particular population group.

18. We therefore recommend purchasing at least 1.5 million additional courses of Pfizer's vaccine. This would total 2.3 million courses with the inclusion of the 800,000 courses we have already secured, enabling us to use it to vaccinate all population groups that the Ministry of Health advises are at heightened risk from COVID-19 (Tiers 1 to 3 in MOH's Sequencing Framework). This would provide certainty that we will be able to offer sufficiently viable vaccines to those groups. It mitigates against the risk that our other candidates may be unsuitable for use in those groups, but does not prevent us from using those vaccines if their Decision to Use assessment is suitably positive.

[1] Novavax has been publicised as around 89% effective. This figure combines its performance against original strains of COVID-19 (95%) and the new UK variant (85%). We have used Novavax's 95% figure as the comparison as we have no information on Pfizer's performance against the UK variant.

Purchase Option 2: Purchase 2.56 million courses to provide greater certainty that we will have sufficient vaccines in 2021

Volume: 5,120,000 doses (2,560,000 courses)
Total Cost: 9(2)(ba)(i)&(ii) million (an additional 9(2)(ba)(i)&(ii) million over Option 1)

19. While our vaccines have generally performed well in clinical trials, there remains a risk that one or more candidates may prove to be unsuitable for use in New Zealand's general population. While we are reasonably confident we will have sufficient quantities of viable vaccines for use in the Immunisation Programme in 2022, we cannot yet guarantee that we will have sufficient quantities in 2021. We could seek to mitigate this risk through purchasing additional quantities of Pfizer's vaccine.

20. This risk has been heightened by the spread of new COVID-19 variants overseas (such as in the United Kingdom, South Africa, and Brazil). This makes an additional Pfizer purchase particularly attractive, as initial data indicates that vaccines that are more effective against original strains are also more effective against the newer variants (early reports indicate that Pfizer has performed well against these variants in a controlled laboratory environment, but we are yet to receive any data for confirmation).

21. With our current delivery schedules, we will have to rely on multiple vaccine candidates if we wish to have 5.36 million courses available to complete the Immunisation Programme in 2021 (either Pfizer + Janssen + Novavax, or AstraZeneca + one or more other portfolio vaccines). This carries several risks as initial reports indicate that AstraZeneca may be less effective against newer COVID-19 variants, and we would not be sure of our ability to reach the 5.36 million wide population coverage target in 2021 for New Zealand and Polynesia with a Pfizer/Janssen/Novavax option if any of those candidates prove to be unsuitable for use.

22. Because we have greater confidence in Pfizer's vaccine than others in our portfolio, we could seek to mitigate risk by purchasing an additional 2.56 million courses. This will provide us with sufficient quantities to immunise our entire population in 2021 if combined with one or more of Janssen, AstraZeneca, or Novavax[2].

23. This approach also insures against delivery slippages. While it is possible that delivery schedules for all our portfolio candidates may be delayed, we are more confident in Pfizer's delivery schedules than those of Janssen and Novavax. Pfizer has already begun manufacturing at scale and, while it encountered several manufacturing 'teething issues' in January, upgrades to its facilities have enabled the company to increase its manufacturing capacity estimates from 1.3 billion to 2 billion doses in 2021. Janssen and Novavax are likely to encounter similar issues when they begin manufacturing later this year, and are therefore more likely to be at risk of delivery slippages (particularly as Novavax has not manufactured at this scale before).

24. Additional Pfizer courses are likely to be valuable even if multiple other portfolio vaccines are suitable for use, and deliver sufficient quantities, in 2021. Our successful elimination strategy has meant that New Zealanders have a very low tolerance for COVID-19 in the community compared with other countries, and may expect a high level of protection before border settings are substantively adjusted. Pfizer's vaccine is one of the most effective currently available on the market. If we immunise a greater proportion of our population with highly effective vaccines (particularly if effectiveness is correlated to

[2] We will have 9(2)(ba)(i)&(ii) Novavax courses and 9(2)(ba)(i)&(ii) Janssen courses in 2021. This means we need at least 9(2)(ba)(i)&(ii) million additional Pfizer courses to reach the 5.36 million target for a Pfizer + Novavax option, or 9(2)(ba)(i) & (ii) courses for a Pfizer + Janssen option. Novavax is scheduled to deliver an additional 9(2)(ba)(i) million courses between 9(2)(ba)(i)&(ii), but these may be subject to delivery slippages.

preventing transmission, as early reports are beginning to indicate), we may potentially be able to reduce our other public health controls to a greater extent.

25. We do not need to decide which vaccines will be used in our Immunisation Programme at this time. However, Pfizer's offer is time limited and we need to act quickly if we wish to secure these doses. While we may be able to purchase additional quantities later in the year, the timeliness of this opportunity may be lost as we are unlikely to able to secure the Q3 and Q4 2021 delivery dates again.

The Ministry of Health does not support Option 2

26. The Ministry of Health does not support Option 2 as it considers there to be no strong public health rationale to purchase more than 1.5 million additional courses. The Ministry of Health's position is that:

    - On current information, the existing vaccine portfolio will support the Immunisation Programme.
    - There is an opportunity cost in purchasing additional vaccines, including fiscal trade-offs and other health interventions.
    - As part of our global responsibilities, there is a need to recognise global vaccine supply constraints. The Ministry considers our current vaccine portfolio to be sufficient for the needs of our population.
    - The logistical complexities and potential limitations for storage and consumables required for Pfizer's vaccine would mean an increased likelihood of vaccine wastage.
    - The Ministry is confident that it can re-enter negotiations as required through our ongoing contractual arrangements with Pfizer.

If either option is pursued, we could seek to use the new purchase to replace our Pfizer courses through the COVAX Facility

27. Joint Ministers recently approved purchasing an additional 50,310 courses of Pfizer's vaccine through the COVAX Facility (MBIE 2021-2132 refers). While this was the only available source of additional quantities of the vaccine at the time, we may now wish to decline the COVAX option and replace these doses by purchasing an additional 50,000 courses bilaterally. COVAX has recently extended the deadline for this decision to 14 February, and we are therefore able to decline the doses without being required to pay for them.

28. New Zealand has received some criticism locally and in international press for committing to purchase doses through the COVAX Facility in the first half of the year, given that we have already secured sufficient doses for population coverage through our four bilateral APAs.

29. We may receive similar criticism if we also purchase additional bilateral doses, which could risk undermining our credibility in multilateral fora. We expect this perception will lessen if we decline the COVAX purchase and only purchase doses through the bilateral offer. The bilateral volumes will deliver from Q3 this year, and it is likely that many other countries will have at least some access to vaccines by that point. The declined COVAX

doses would be reallocated to other participants, reducing the risk that we are seen to be taking doses from countries that may have a greater need for them.

30. 6(b)(ii) [redacted]

31. Such an approach may also have a limited impact on our Pfizer delivery schedules. The COVAX offer will deliver between Q2 and Q4, with deliveries potentially beginning a quarter earlier than the new bilateral offer. However, our experience with COVAX to date suggests that countries will receive their doses incrementally over 2021, so any COVAX doses delivered in Q2 are likely to be highly limited.

32. Regardless of whether we decline the COVAX option, we can further mitigate the risk of reputational damage by making early assessments of whether New Zealand will use vaccines in our portfolio, and redirecting doses that are surplus to our needs to the Pacific and other developing countries.

We are considering measures to manage the portfolio going forward, including vaccine donation

33. As the Immunisation Programme progresses we expect to have several options to manage our vaccine portfolio going forward. These options will also be shaped by new information on vaccines in our portfolio and in development, and as more information becomes available on the COVID-19 virus and its newer variants.

34. These options are likely to include:

- Consideration of additional vaccine purchase opportunities (particularly for later stage or updated vaccines)
- Seeking to adjust delivery schedules and purchase arrangements with suppliers, so that we are able to access updated versions of existing vaccines (which may potentially be more effective against newer COVID-19 variants).
- Donation of vaccines to support the Pacific and to ensure that we are supporting equitable global access to vaccines.

35. If Joint Ministers approve an additional Pfizer purchase, the Ministry of Health will provide further advice on managing the portfolio. This will include whether we donate the doses of AstraZeneca's vaccine that we purchased through the COVAX Facility (843,000 courses), or potentially seek to adjust the delivery schedules for that purchase.

36. 9(2)(ba)(i) & (ii) [redacted]

Next steps

37. With Joint Ministers' approval, we will immediately begin negotiations with Pfizer to purchase the agreed volumes. We expect these negotiations will be straightforward as

the offer will be covered by the same terms and conditions as our bilateral APA. We will then return for Joint Ministers' approval to sign the final purchase agreement and to draw down the necessary funding.

38. We will provide advice to Joint Ministers on future purchase opportunities as these arise and new information becomes available.

Annexes

Annex One: Overview of vaccine purchasing contingency

Annex Two: Pfizer Science and Clinical Review Panel commentary

Annex One: Overview of vaccine purchasing contingency

Developer/source	Courses	Funding required[3] ($m NZD)	Cumulative funding required ($m NZD)	Comments
Existing Purchases				
Pfizer/BioNTech (mRNA)	750,000	[redacted]	[redacted]	
Janssen Pharmaceuticals (viral vector)	5,000,000	[redacted]	[redacted]	
University of Oxford/AstraZeneca (viral vector)	4,634,000	[redacted]	[redacted]	Includes 6(b)(ii) for COVAX doses
Novavax (protein subunit)	5,360,000	[redacted]	[redacted]	
COVAX Facility: upfront payment and risk-sharing guarantee	—	35.00	[redacted]	$35.0m drawn down as costs were still to be determined by COVAX at the time. $26.88m has since been paid to COVAX.
Pfizer/BioNTech (COVAX doses)	50,310	[redacted]	[redacted]	If we decline the COVAX option, we would seek to purchase an additional 50,000 courses bilaterally, at an alternative total cost of $3.65 million.
Bilateral Pfizer Purchase Options				
Option 1	**1,500,000**	[redacted]	[redacted]	
Option 2	**2,560,000**	[redacted]	[redacted]	
Total vaccine purchasing contingency: $983.70 million[4]				
Contingency remaining after Pfizer purchase: 9(2)(ba)(i)&(ii) (Option 1) 9(2)(ba)(i)&(ii) (Option 2)				

[3] Appropriated funding includes provision for foreign exchange rate fluctuations

[4] This total does not include funding appropriated from the overall contingency for delivery of the immunisation programme.

Annex Two: Science and Clinical Review Panel Commentary on Pfizer's COVID-19 vaccine candidate

Trial data update – 15 December 2020

Phase 1/2 data presented by Pfizer for their vaccine candidate BNT162b2 on September 1st 2020 were promising, with all 23 participants (18-85yo) vaccinated with 30ug dose (which will be used in the vaccine) producing neutralising antibody. These participants had a higher average level (geometric mean titre) of neutralising antibody than 38 people with prior infection with the COVID-19 virus (35 of whom were symptomatic). This immune response was dose-dependent as expected, but was also reduced in older people (55-85yo) compared to younger adults (18-55 yo). However, both age groups had higher average neutralising antibody levels than those with prior infection. Overall, reactions (e.g. injection site swelling, post-vaccination fever) to this vaccine were common but generally self-limiting and not severe, with 15%, 18% and 25% of 18-55 year olds experiencing moderate fatigue, fever and myalgia respectively after 2 doses, and 10%, 0% and 0% experiencing severe fatigue, fever and myalgia. Reactogenicity was lower in the older age group.

This vaccine moved forward in to phase 2/3 efficacy trials in July 2020, with data currently available for approximately 38,000 16-85yo people (around 19,000 vaccinated) in USA, Argentina, Brazil, Germany, South Africa, and Turkey. Reactogenicity in a subset of 8000 people was broadly similar to previous trials, with 34%, 5% and 22% experiencing moderate fatigue, fever and myalgia respectively (after 2 doses in 16-55yo, with slightly lower reactogenicity in those over 55y), and 5%, 2% and 3% experiencing severe fatigue, fever and myalgia. Antipyretics were used by 45% of vaccinated subjects after vaccination. Other safety outcomes were reported after follow-up of mean duration of 2 months after the second dose (maximum 14 weeks). Four vaccine-related serious adverse events were reported among BNT162b2 recipients (shoulder injury related to vaccine administration, axillary lymphadenopathy, paroxysmal ventricular arrhythmia, and leg paraesthesia). No deaths were considered by the investigators to be related to the vaccine or placebo (of a total 2 deaths in vaccinated, 4 in placebo), and withdrawals from the study were similar in vaccinated and placebo groups.

Vaccine efficacy (modified intention to treat cohort) against symptomatic, lab confirmed (NAAT test) COVID-19 at least 7 days after the second dose was 95% (95% credible interval 90.3%-97.6%) among those with no evidence of prior infection with the virus and 94.6% (89.9%-97.3%) when those with evidence of prior infection (around 10% of participants) were included. Some protection from disease was apparent in the vaccinated group before the second dose. These efficacy figures relate to 8 vaccinated vs 162 placebo cases in those with no evidence of prior infection, and 1 vaccinated vs 7 placebo cases in those with evidence of prior infection. The single severe vaccinated COVID-19 case occurred approximately 40 days after the second dose. In the placebo group, there were 9 severe cases, with 4 of these occurring between the first and second dose, 1 around the time the second dose was given, and 4 more than 1 week after the second dose. Supplemental analyses indicated that vaccine efficacy among subgroups defined by age, sex, race, ethnicity, obesity, and presence of a coexisting condition was generally consistent with that observed in the overall population, although some groups (e.g. over 65 and obese) had too few events to provide a precise estimate. Those with HIV were excluded from these analyses, and there were no pregnant women included in the study. A small number of 12-15 year olds were included in the study, with no cases of COVID-19 were observed in vaccinated or placebo groups, precluding meaningful vaccine efficacy calculations.