Request that the Minister of Finance give an indemnity in favour of Novavax under section 65ZD of the Public Finance Act 1989

Introduction

1. Novavax has offered New Zealand 5.36 million courses of its vaccine candidate (known as NVX-CoV2373) 9(2)(ba)(i) & (ii) . This is considered sufficient for broad population cover in New Zealand and Polynesia, factoring in 15 percent for wastage.

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

3. 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.

4. Officials believe there is a strong rationale to sign the purchase agreement because:

   a. 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.

   b. 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.

   c. 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.

   d. While there are inherent risks to the delivery time of all vaccine candidates, delivery is expected to start from 9(2)(ba)(i) & (ii) . This timeframe is suitable for the immunisation programme. 9(2)(ba)(i) & (ii)

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

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

e. It is expected to be straightforward to deliver using familiar cold chain systems.

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

g. 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) & (ii)

h. 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.

5. 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.

6. The terms of Novavax's offer to sell the vaccines to New Zealand are contained in the legally binding Advance Purchase Agreement (APA) attached as Annex One. 9(2)(ba)(i) & (ii)

7. As part of the APA Novavax is seeking an indemnity from the Crown 9(2)(ba)(i) & (ii)

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

8. Novavax is seeking an indemnity because:

(a) they are developing the vaccine in accelerated clinical trials that are less likely than non-accelerated trials to detect uncommon adverse effects or possible contraindications;[4]

[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.

[4] Novavax 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

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

9. This document sets out the business case for the indemnity that we have negotiated, taking into account advice from our external legal adviser Bell Gully.

Background

10. It is not unexpected for pharmaceutical companies to seek indemnities from governments in circumstances where clinical trials are restricted, or approval is granted before full trials are completed.

11. The Minister of Finance granted an indemnity in favour of Pfizer/BioNTech on 5 October and signed a deed of indemnity in favour of AstraZeneca on 7 December, both as part of purchase agreements for COVID-19 vaccines.

12. Indemnity clauses are also common in APAs between pharmaceutical companies and governments internationally for the supply of pandemic influenza vaccines. The Minister of Finance has given an indemnity in relation to influenza vaccine on four occasions.

Our aim in negotiations on indemnity is to minimise the Crown's liability

13. In order to minimise the Crown's liability, in negotiations with pharmaceutical companies we are seeking 9(2)(j)

9(2)(j)

Scope of the indemnity

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).

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

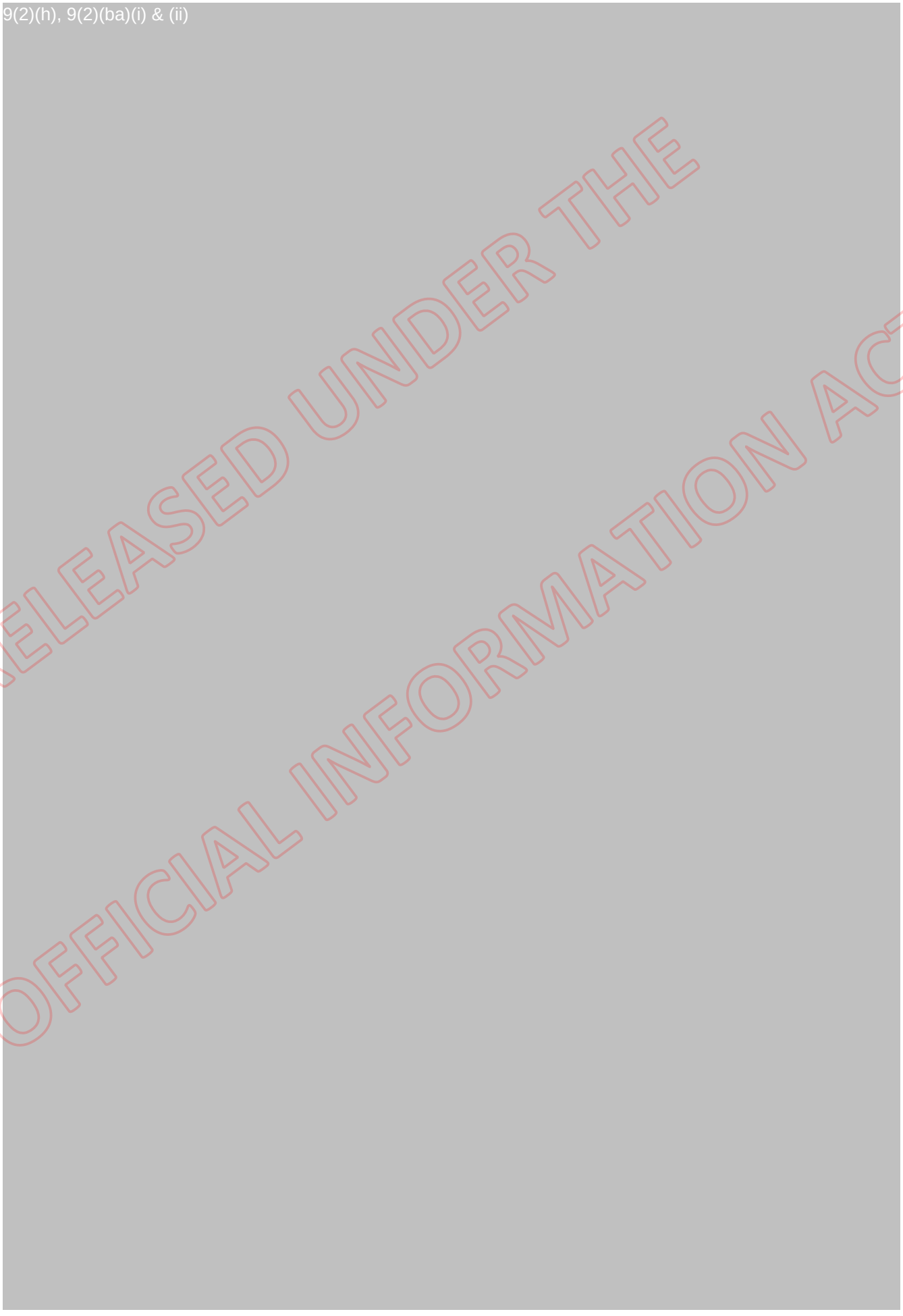
9(2)(ba)(i) & (ii)

17. Bell Gully has provided the following explanation of the provisions:

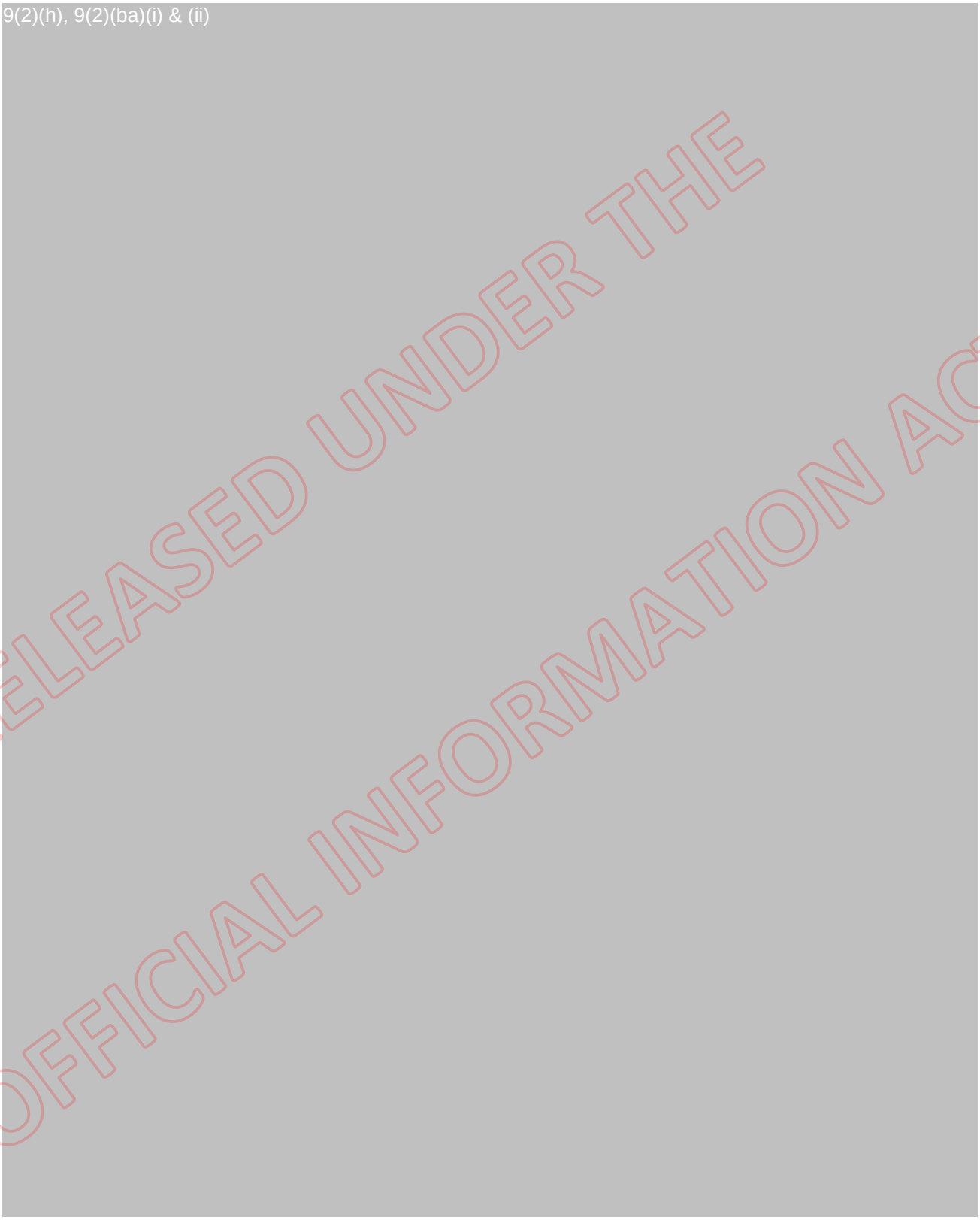
9(2)(h), 9(2)(ba)(i) & (ii)

[5] 9(2)(h), 9(2)(ba)(i) & (ii)

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



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



24. A table comparing the Novavax, Pfizer, Janssen and AstraZeneca indemnities is attached at Annex Two.

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

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

Exposure, risk and mitigation

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

ACC will cover most of the Crown's liability for adverse effects associated with use of the vaccine

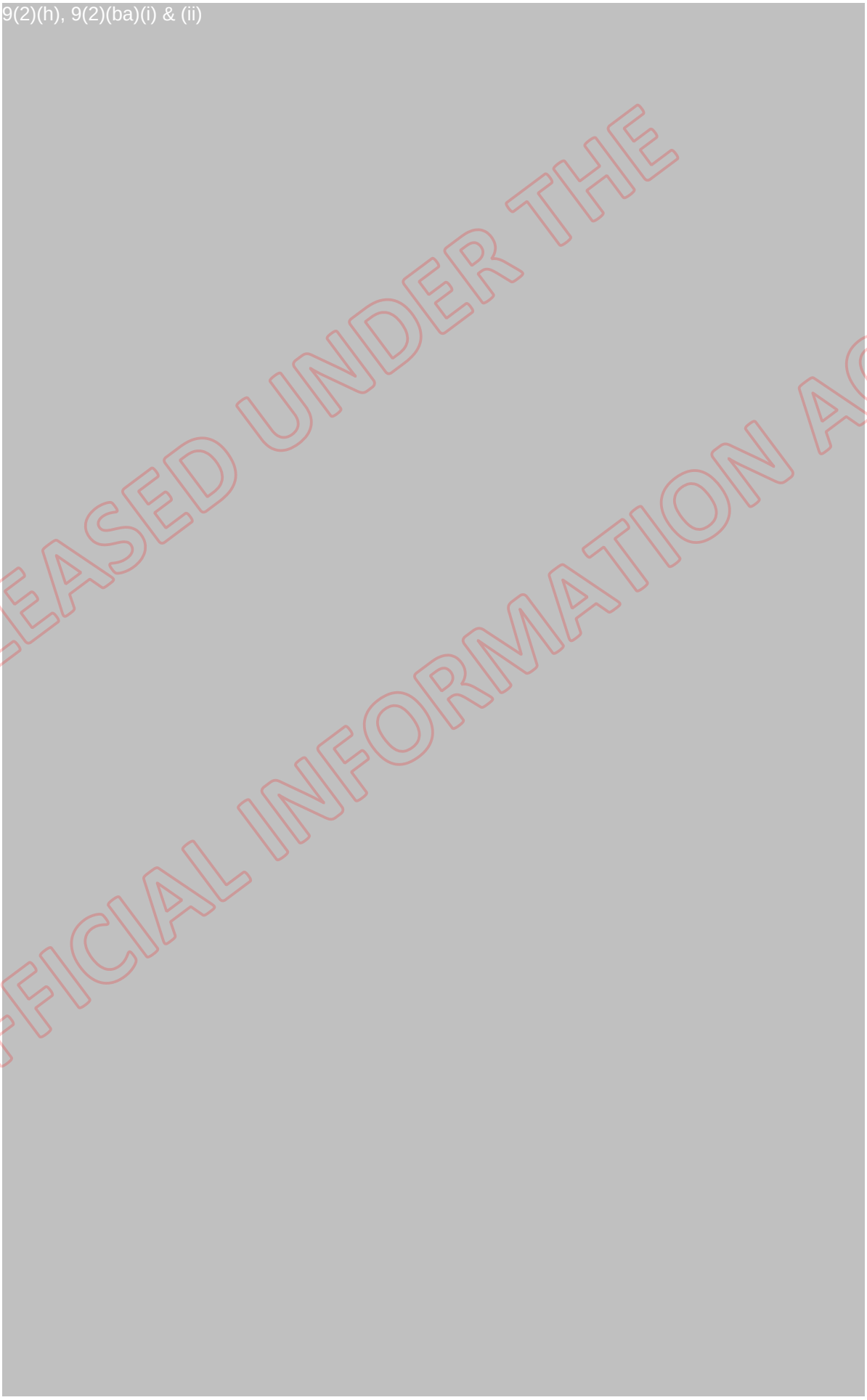
28. ACC can cover personal injuries arising from the administration of a vaccine by a registered medical professional.[6] Costs to ACC related to use of the vaccine in New Zealand will arise regardless of the provision of contractual indemnity.

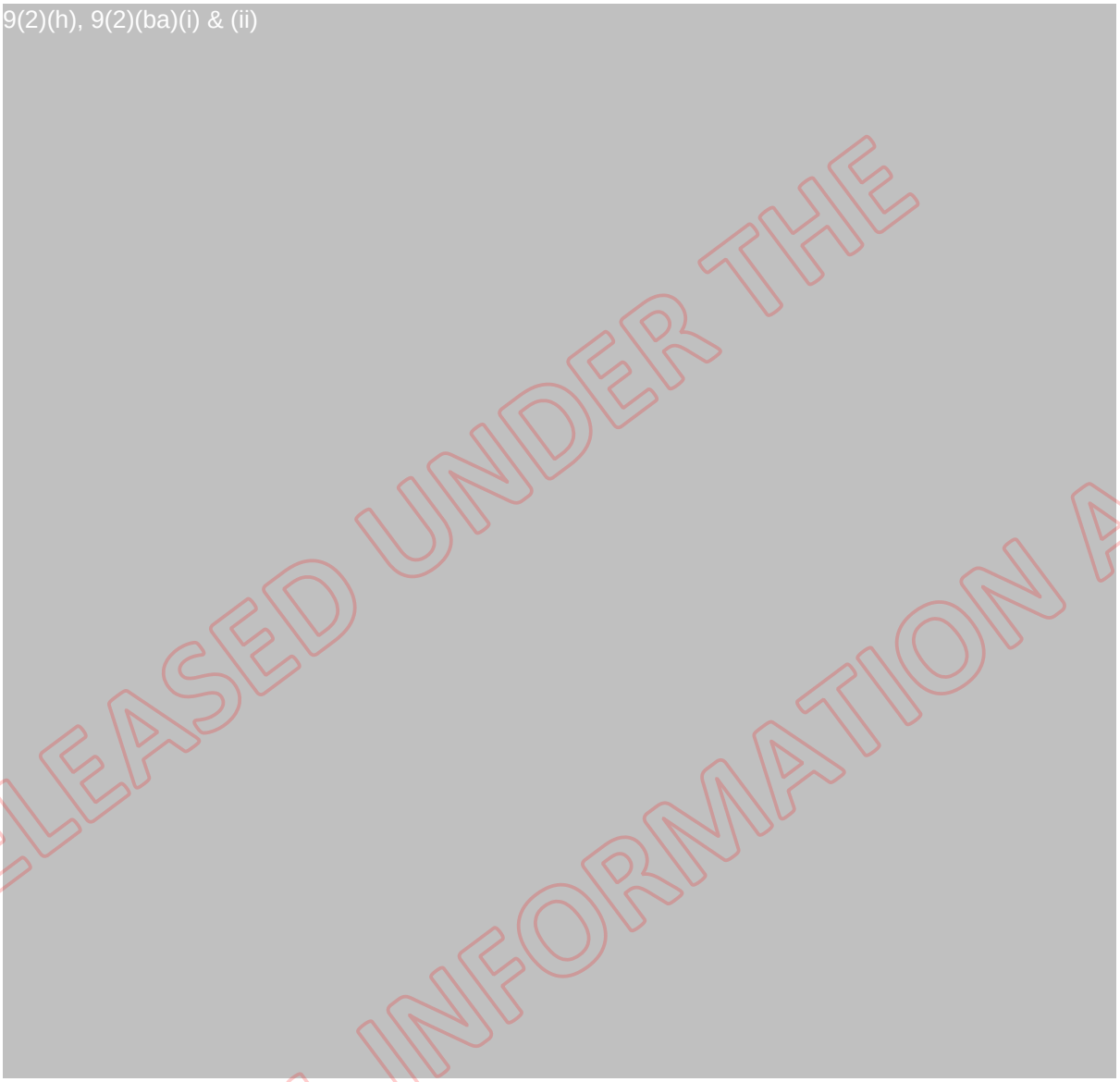
The liability associated with claims not covered by ACC is relatively low-risk

29. Bell Gully has advised that "overall, the risks associated with claims 9(2)(h), 9(2)(ba)(i) & (ii) which would not be covered by the AC Act seem likely to be relatively low (particularly when assessed against the risks of not accessing a vaccine), with the Crown able to take certain steps to protect its position as far as possible. However, the exact risk in each case will depend upon the nature of the vaccine (including its efficacy and side effects) as well as how widely the vaccine is ultimately used in the population.

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

[6] Access to cover depends on the circumstances of the injury – including that there must be a clear causal link between the treatment and the injury, and the injury must not be a necessary part or ordinary consequence of the treatment.





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

9(2)(j)

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

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

38. Bell Gully advises that it is not possible at this stage to estimate the maximum potential liability the Crown could incur under the Novavax indemnity because "there remains too great a range of uncertainties, including around the risks associated with the vaccine and its side effects, its physical properties and how it will be deployed in New Zealand."

There are measures in place to mitigate the risk of injuries

39. As noted above, ACC cover is likely to be available for most injuries caused by the vaccine. Injuries could also, however, result in claims not barred by the Accident Compensation Act – for example claims for 9(2)(ba)(i) & (ii) – though as noted above, Bell Gully considers these risks to be relatively low.

40. Measures to mitigate the risk of injuries include:

- Medsafe will be undertaking a **risk-benefit assessment** as part of the regulatory approval process to ensure the vaccine meets internationally accepted criteria for safety, quality and effectiveness. Medsafe will also be seeking its own independent expert advice and will work with regulators globally (eg the US Food and Drug Administration, European Medicines Agency and Australian Therapeutic Goods Administration) to assess the safety and efficacy of the vaccine.
- 9(2)(ba)(i) & (ii)
- Medsafe is developing a strategy for **monitoring the vaccine once it is being used**. This may include adverse reaction reporting, active monitoring (via SMS text and real time analysis), requirements on companies to provide adverse reaction information globally, and sharing monitoring data with other regulators to identify safety issues. This monitoring will allow Medsafe to take timely action if a safety issue emerges.
- Replacement of the National Immunisation Register with a new **National Immunisation Solution** (expected in Q1 2021) to monitor who has received doses of the vaccine.
- Requirements on the supplier to have a **risk management and post-marketing surveillance programme** 9(2)(ba)(i) & (ii)

We are working to mitigate additional risks associated with the indemnity

41. A key aspect of our communications and engagement approach is to **acknowledge that public expectations of potential vaccines may be unrealistic**, and to **actively manage these expectations** as part our stakeholder and public communication. This will help to mitigate the risk of any claims relating to an ineffective vaccine or negligent misstatement.

42. The indemnity could **reduce public confidence in the vaccine** and therefore reduce uptake. This might cause a flow-on in **reduced public confidence in vaccines in general**, potentially reducing immunisation rates for other diseases. This could ultimately result in reduced public confidence in the government and the health system.

43. To mitigate this risk, which will apply to all indemnities in APAs, we are seeking to limit the scope of indemnity provisions as far as possible. In addition, we will develop key messaging that provides context around the potential issue of indemnity in the event of public or media interest (noting that the indemnity will be public knowledge at some stage because the Minister of Finance is required to table a statement about the indemnity in the House as soon as practicable after giving the indemnity. Such statements have already been tabled in relation to the APA with Pfizer and our participation in the COVAX Facility).

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

47. 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.

48. However, Novavax's international partnerships provide assurance of its ability to develop and manufacture the vaccine. Novavax has:

- secured US$2 billion in funding from Operation Warp Speed (a United States government programme) and the Coalition for Epidemic Preparedness

[7] 9(2)(ba)(i) & (ii)

Innovations (CEPI) for late stage clinical development and to establish large-scale manufacturing;

- engaged the Serum Institute of India to manufacture one billion doses in 2021.

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

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

Termination Arrangements

53. 9(2)(ba)(i) & (ii)

Necessary or Expedient in the Public Interest

54. The Public Finance Act says that the Minister of Finance may grant an indemnity if it appears to the Minister to be necessary or expedient in the public interest.

The indemnity is in the interest of the New Zealand public because its benefits outweigh its risks

55. The meaning of "public interest" depends on the circumstances and can be multi-faceted, but it is generally accepted that it is broadly equivalent to the public good or what is in the best interests of society. In the context of the Public Finance Act the public interest can be viewed as the interest of the New Zealand public.

56. We judge that the indemnity is in the interest of the New Zealand public because the benefits that it will bring to New Zealand (outlined below) outweigh the relatively low risks to the Crown that Bell Gully has identified (described in the "exposure, risks and mitigation" section).

The key benefit of the indemnity is that it will allow New Zealand to conclude a bilateral APA with Novavax

57. An APA with Novavax will in turn bring the below benefits to the Crown and to the New Zealand public.

58. An APA with Novavax will contribute to our portfolio of APAs for promising vaccine candidates.

59. 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.

60. The vaccine could play an important role in the portfolio by providing broad population cover and limiting the risk of technology failure:

    a. 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.

    b. Similar to Janssen's and AstraZeneca's vaccine, 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.

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

62. The vaccine could bring economic and social benefits to New Zealand if it is successful and Medsafe judges it to be safe and effective for use in New Zealand, and it is rolled out as part of the immunisation programme.

63. Immunisation could help reduce severity of illness among those who are vaccinated, ensure our health system is not overwhelmed, and provide a level of immunity from COVID-19. Achieving population immunity from COVID-19 and reducing transmission

rates will also reduce and potentially eliminate our reliance on blunter tools like border controls and lockdowns.

Economic impacts

64. The main economic impacts of a successful vaccine roll-out would be to reduce the risks of entering high alert levels and the economic costs associated with those levels, and to enable a relaxation of border restrictions. Immunisation is the only public health tool that would reduce the level of threat posed by COVID-19, rather than shielding against the disease as our other tools (e.g. isolation, testing, restrictions on movement) are designed to do.

65. If a successful vaccine or therapeutic sufficiently reduced the level of threat posed by COVID-19, and thus contributed to a relaxation or eventual removal of border restrictions, we do not anticipate an immediate recovery in international travel to levels seen prior to the COVID-19 pandemic. This reflects negative impacts on household income and a possible change in traveller behaviours, while it may take some time for capacity on international air routes to be re-established.

66. The Treasury estimates that nationwide Alert Level controls have the following impacts on GDP:

Level 4	25%-30%
Level 3	15%-20%
Level 2	6%-10%
Level 1	3%-5%

Note the estimated economic costs of different Alert Levels are based on historical data, and do not reflect how firms and households adapt behaviour, nor do they reflect the changes in Government policy.

67. The Pre-election Economic and Fiscal Update (PREFU), assumes a combination of Alert Level 3 and 2 restrictions lasting approximately four weeks in the September 2020 quarter. Alert Level 1 restrictions are then assumed to apply until 1 January 2022.

68. The main scenario in PREFU assumes that border restrictions are to be lifted on 1 January 2022. However, travel services exports, including tourism and international education services, are assumed to start recovering from the September 2021 quarter onwards, reflecting the possibility of safe travel arrangements being agreed. This will allow some services exports and non-New Zealander net migration to resume. However, the effects of COVID-19 will continue to be far-reaching and the pace at which services exports such as tourism and international education will recover remains uncertain.

69. 9(2)(ba)(i) & (ii) [redacted]

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

71. 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].

72. We are working through the issues that provision of vaccine to Pacific countries would raise, which 9(2)(ba)(i) & (ii) include distribution of vaccine doses, additional support required, ensuring the vaccines are appropriate for the Pacific environment, and how the transfer of funding and/or cost-sharing might be operationalised.

Granting the indemnity to Novavax is expedient in the public interest

73. The word "expedient" is not defined in the PFA but Crown Law has advised that there is authority in differing contexts that it means "fitting", "suitable", "desirable" or "convenient".

74. Granting the indemnity in order to conclude an APA with Novavax is expedient because it will help us achieve our Vaccine Strategy objective of securing enough safe and effective vaccines for New Zealand and Polynesia,[8] in the current circumstances where:

- we have to move quickly and pragmatically to secure APAs in an environment of unprecedented global demand;
- all pharmaceutical companies are seeking indemnities in APAs.

75. In order to achieve our Vaccine Strategy objective, we need a portfolio containing at least four candidates with diverse technology platforms and characteristics, in quantities sufficient for broad population cover.

76. To have the best chance of achieving population immunity from COVID-19 as soon as possible, we need to purchase vaccines through bilateral APAs. This route offers faster access to vaccines than others would (eg purchasing vaccines solely through the COVAX Facility, which is capped at doses for 50 percent of our population with an uncertain end date for delivery; it is also not yet clear whether the Novavax vaccine candidate will be available through COVAX). Domestic manufacturing of COVID-19 vaccines is also not viable in the short term, because vaccine developers we have been in negotiations with have already made manufacturing arrangements for the vaccines they intend to produce in the next year or two.

77. At this stage our portfolio is still under construction. So far we have two vaccine candidates that can offer broad population cover: five million courses of the Janssen vaccine candidate, a viral vector vaccine, and 3.8 million courses of the AstraZeneca candidate (another viral vector vaccine), which we are seeking to supplement with a top-up purchase through the COVAX Facility (briefing MBIE-2021-0858 refers).

78. An agreement with Novavax would populate the portfolio with a third candidate in sufficient quantities to provide broad population cover, on a different technology platform.

79. We also have 750,000 courses of an mRNA vaccine candidate from Pfizer Inc. 9(2)(ba)(i) & (ii)

[8] Cabinet agreed to the COVID-19 Vaccine Strategy in May 2020. The objective is to secure access to sufficient quantities of safe and effective COVID-19 vaccines to implement a preferred immunisation programme at the earliest possible time.

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

80. 9(2)(ba)(i) & (ii) we will investigate the purchase of another high-volume candidate and continue to consider smaller purchases, including through the COVAX Facility.

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

- We would 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. 9(2)(ba)(i) & (ii)

Overall judgement

82. We judge that the benefit of the APA to New Zealand outweighs the risk and justifies granting the indemnity.

83. 9(2)(ba)(i) & (ii)

- the risks associated with claims 9(2)(ba)(i) & (ii) which would not be covered by the AC Act seem likely to be **relatively low**;
- 9(2)(ba)(i) & (ii)

Risk Management

84. The Ministry of Health and other agencies are putting in place the risk management measures as outlined in the “Exposure, Risk and Mitigation” section above.

Other considerations

85. The business case reflects specific legal advice (legally privileged) from Bell Gully and Crown Law as referred to in the text. Bell Gully has also reviewed this document.

Responsible Minister Briefing

86. We are briefing responsible Ministers in parallel with submitting the business case to the Treasury, in order to conclude the agreement with Novavax as quickly as possible. Novavax’s offer is time-limited, and the purchase agreement needs to be concluded

without delay because New Zealand's vaccine allocation is held temporarily from the global allocation.

Notification Requirements

87. We have provided a draft notice for the indemnity because the exposure is unquantifiable. This statement is intended to be tabled in the House of Representatives once the indemnity is given, and the Definitive Agreement is signed.

Statement of Indemnity given under the Public Finance Act 1989

Pursuant to section 65ZD(3) of the Public Finance Act 1989, the Minister of Finance makes the following statement:

On [date] I, Grant Robertson, Minister of Finance, on behalf of the Crown, gave an indemnity in favour of Novavax, Inc and specific associated persons in an Advance Purchase Agreement for the supply of NVX-CoV2373, a vaccine intended to prevent SARS-CoV-2 ("COVID-19") in humans.

Dated at Wellington this [insert date of month] day of [insert month] [insert year].

Hon Grant Robertson
Minister of Finance

Recommendation

The Ministry of Business, Innovation and Employment and the Ministry of Health recommend that the Minister of Finance approve the giving of the indemnity in favour of Novavax on the terms contained in the supply agreement in Annex One.

Peter Crabtree
Delegate of Chief Executive Carolyn Tremain
Ministry of Business, Innovation and Employment

Maree Roberts
Deputy Director-General, System Strategy and Policy
Delegate of Director-General and Chief Executive Dr Ashley Bloomfield
Ministry of Health

Annex One: supply agreement

Annex Two – indemnities comparison (supplied by Bell Gully)

	Pfizer Indemnity	Janssen Indemnity	AstraZeneca Indemnity	Novavax Indemnity
9(2)(ba)(i) & (ii)				

	Pfizer Indemnity	Janssen Indemnity	AstraZeneca Indemnity	Novavax Indemnity
9(2)(ba)(i) & (ii)				

	Pfizer Indemnity	Janssen Indemnity	AstraZeneca Indemnity	Novavax Indemnity
9(2)(ba)(i) & (ii)				