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

Introduction

1. Negotiations have concluded on an agreement for the supply of vaccines from AstraZeneca Limited ("AstraZeneca").

2. 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) & (ii) course 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) & (ii) million (which requires a total of 9(2)(ba)(i) & (ii) million to be set aside to address foreign exchange risk).[2] 9(2)(ba)(i) & (ii)

3. 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 viral platform for malaria, HIV, influenza, hepatitis C, tuberculosis, Ebola and others.

4. 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.

5. While there are inherent risks to the delivery time of all vaccine candidates, there is a potential to receive a large number of vaccines before the end of 2021, which would support efforts to prevent and manage health risks associated with COVID-19 in a timely manner. 9(2)(ba)(i) & (ii)

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

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

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

   b. 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

[1] The candidate works by carrying DNA into human cells that then produce vaccine (SARS-CoV-2 virus spike protein antigen). 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) & (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.

New Zealand. This gives us confidence in their ability to develop, manufacture and deliver a vaccine to prescribed standards.

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. 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.

e. 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, should this be desirable for New Zealand's immunisation strategy.

f. 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 may be effective against asymptomatic infection. Recent research indicates that almost half of all people infected with COVID-19 are asymptomatic.

g. 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.

8. 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.

9. 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. 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.

10. As part of the supply agreement AstraZeneca is seeking an indemnity [redacted] 9(2)(ba)(i) & (ii)

[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 15 million courses and the EU has purchased 150 million courses.

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

11. AstraZeneca is seeking the 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]

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

12. 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

13. 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.

14. On 5 October the Minister of Finance granted an indemnity in favour of Pfizer Inc and BioNTech as part of an APA for the purchase of their COVID-19 vaccine, BNT162.

15. Joint Ministers have also agreed to non-binding Heads of Terms (including an indemnity along similar lines to the Pfizer indemnity) for an APA with Janssen Pharmaceutica NV ("Janssen").

16. 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

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

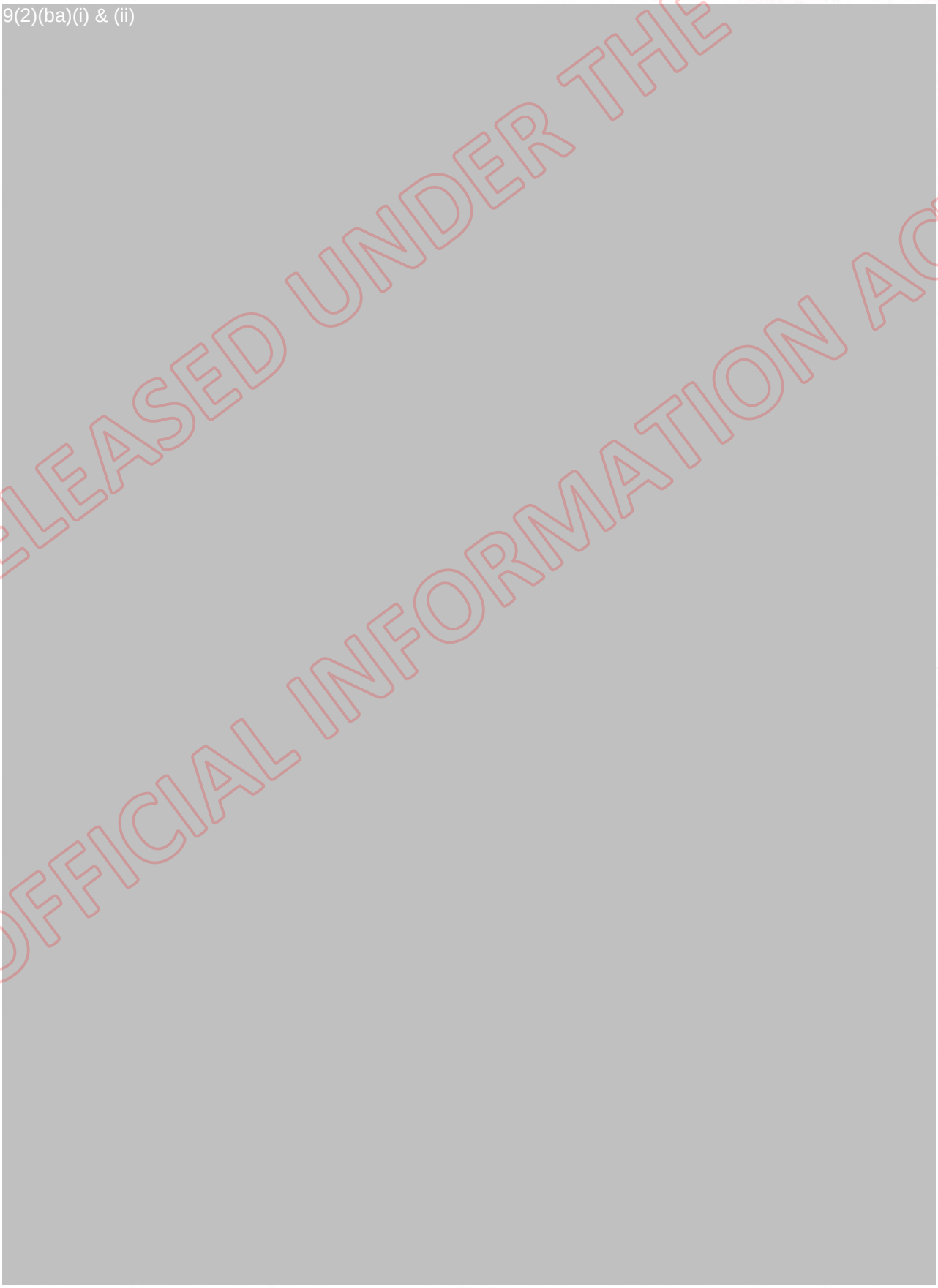
[4] AstraZeneca will provide Medsafe with full clinical trials information when they apply for regulatory approval. Study designs and regulatory approaches will vary between COVID-19 vaccine applicants, but most trials will be shorter in length and study fewer people than what is typical. The impact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

9(2)(j)

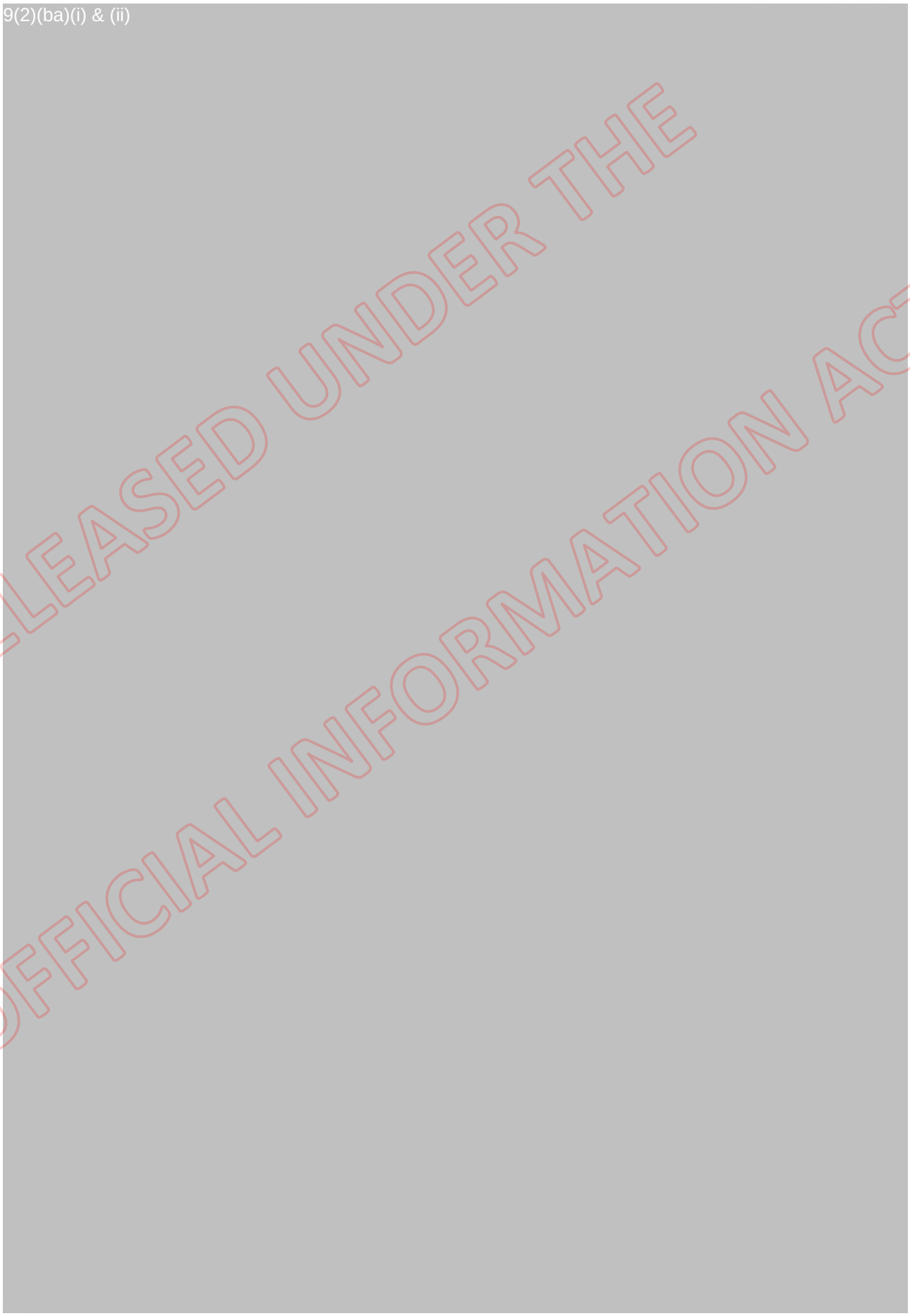
Scope of the indemnity

19. The indemnity reads:

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



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



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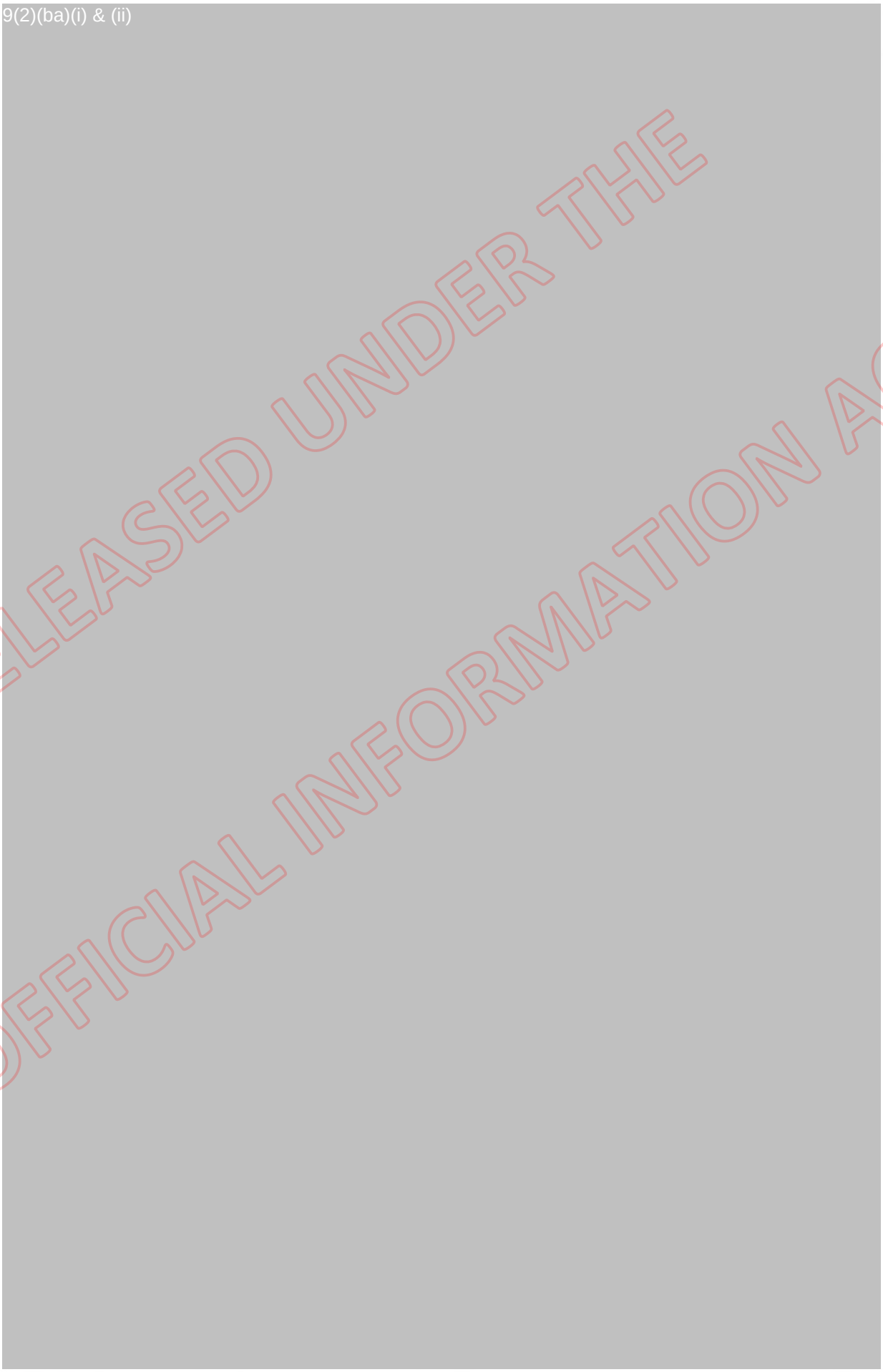
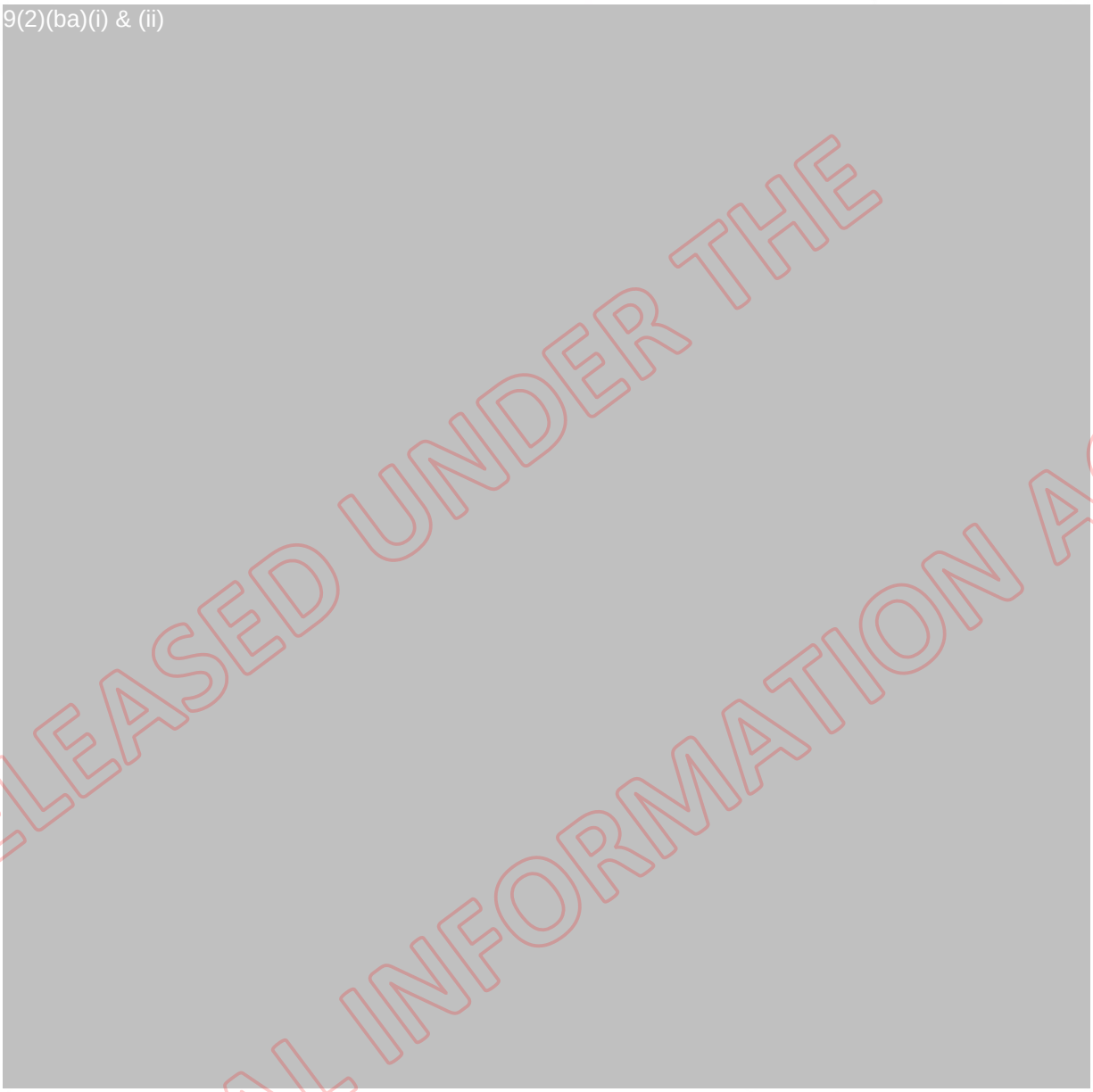
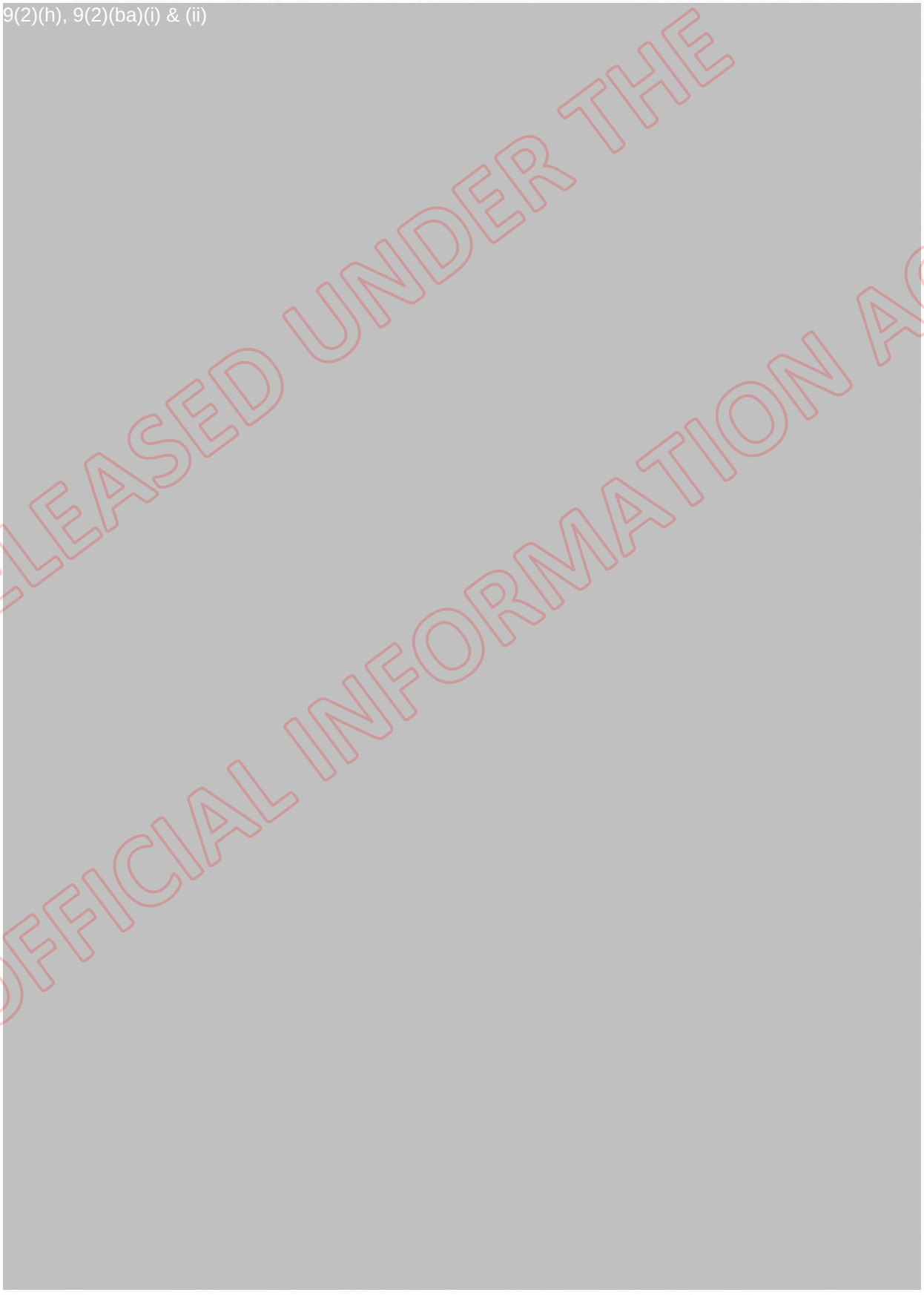


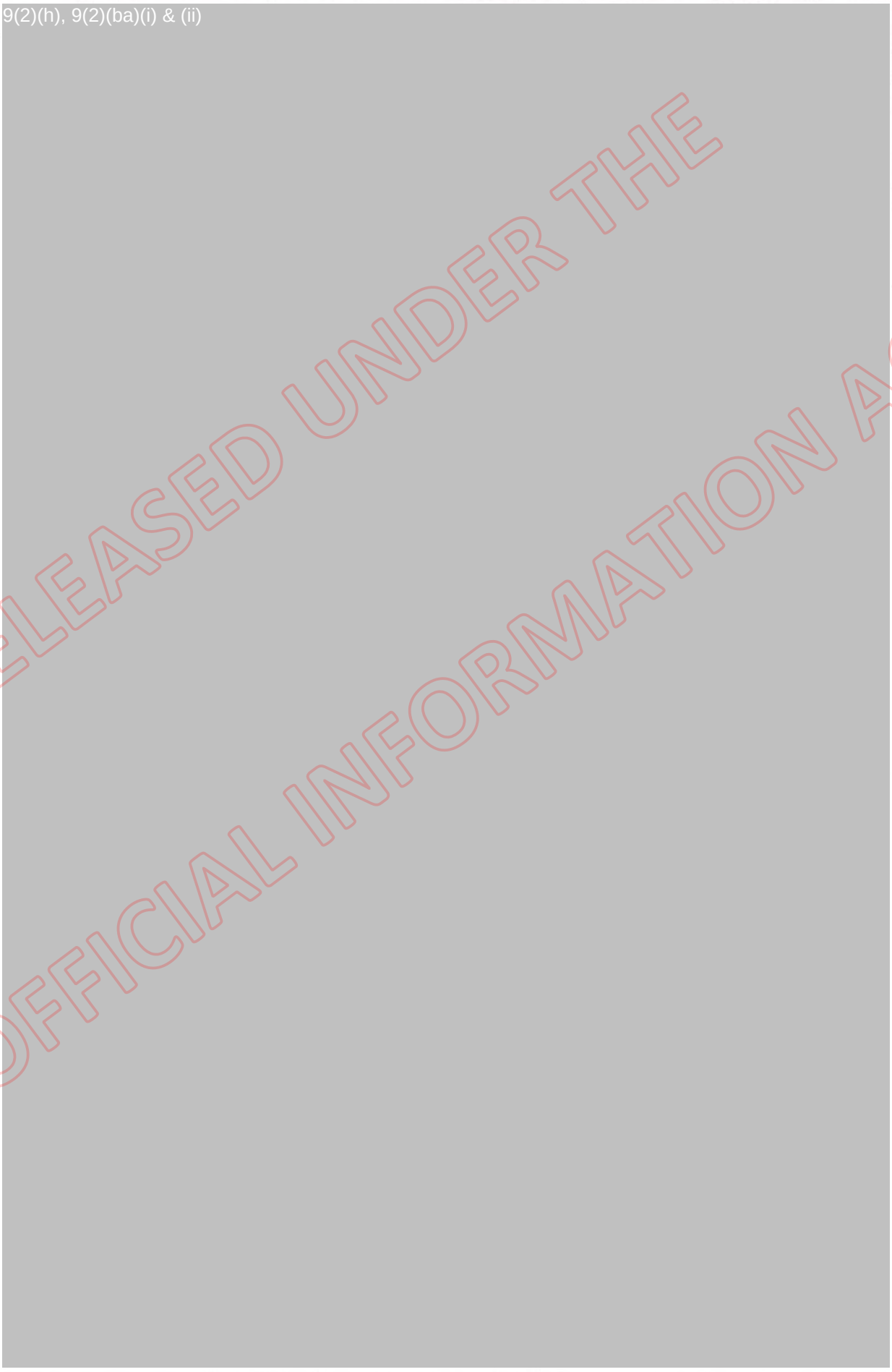


20. Bell Gully has provided the following explanation of the provisions:

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



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



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

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

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

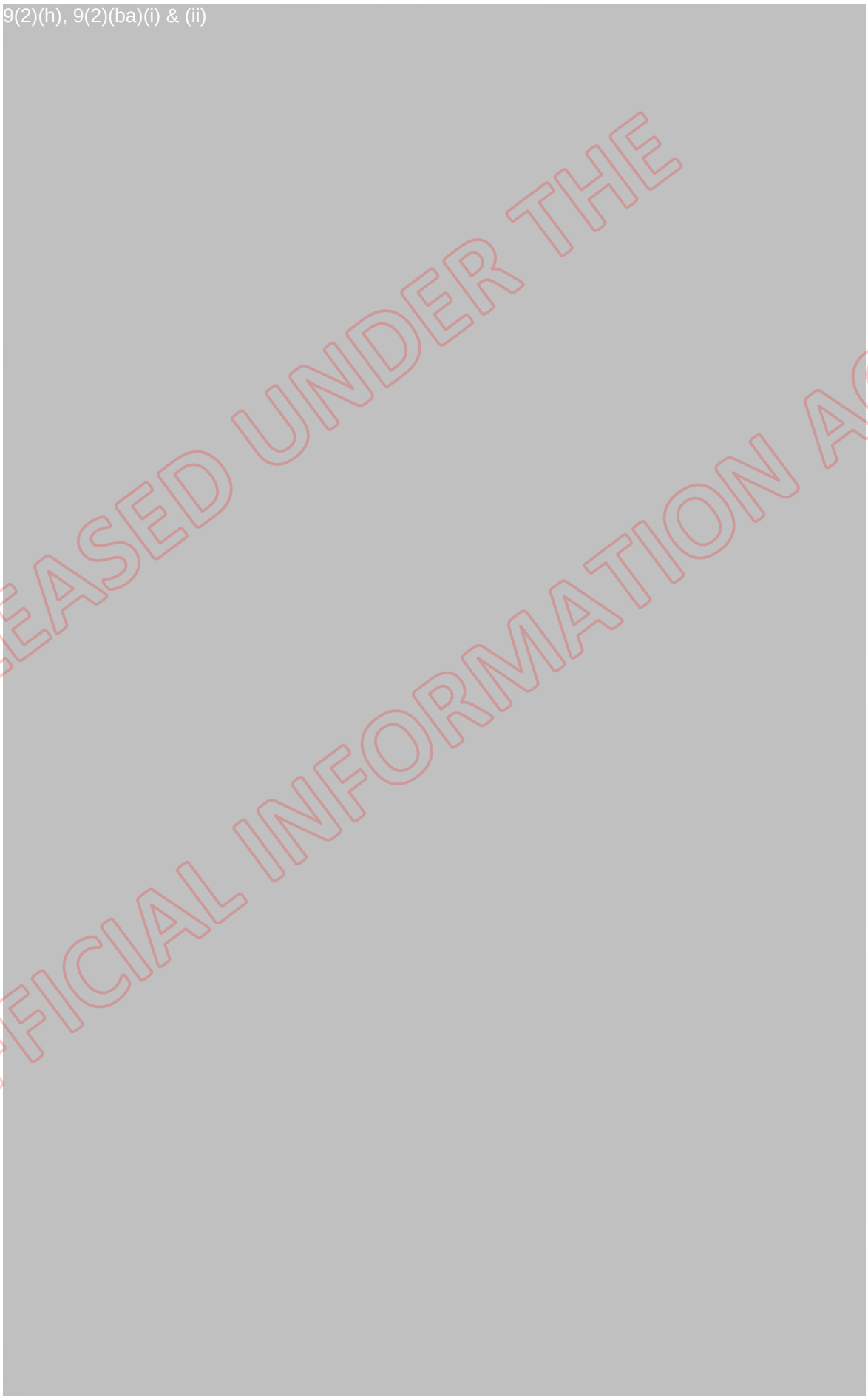
31. ACC can cover personal injuries arising from the administration of a vaccine by a registered medical professional.[5] Costs to ACC related to use of the vaccine in New Zealand will arise regardless of the provision of contractual indemnity.

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

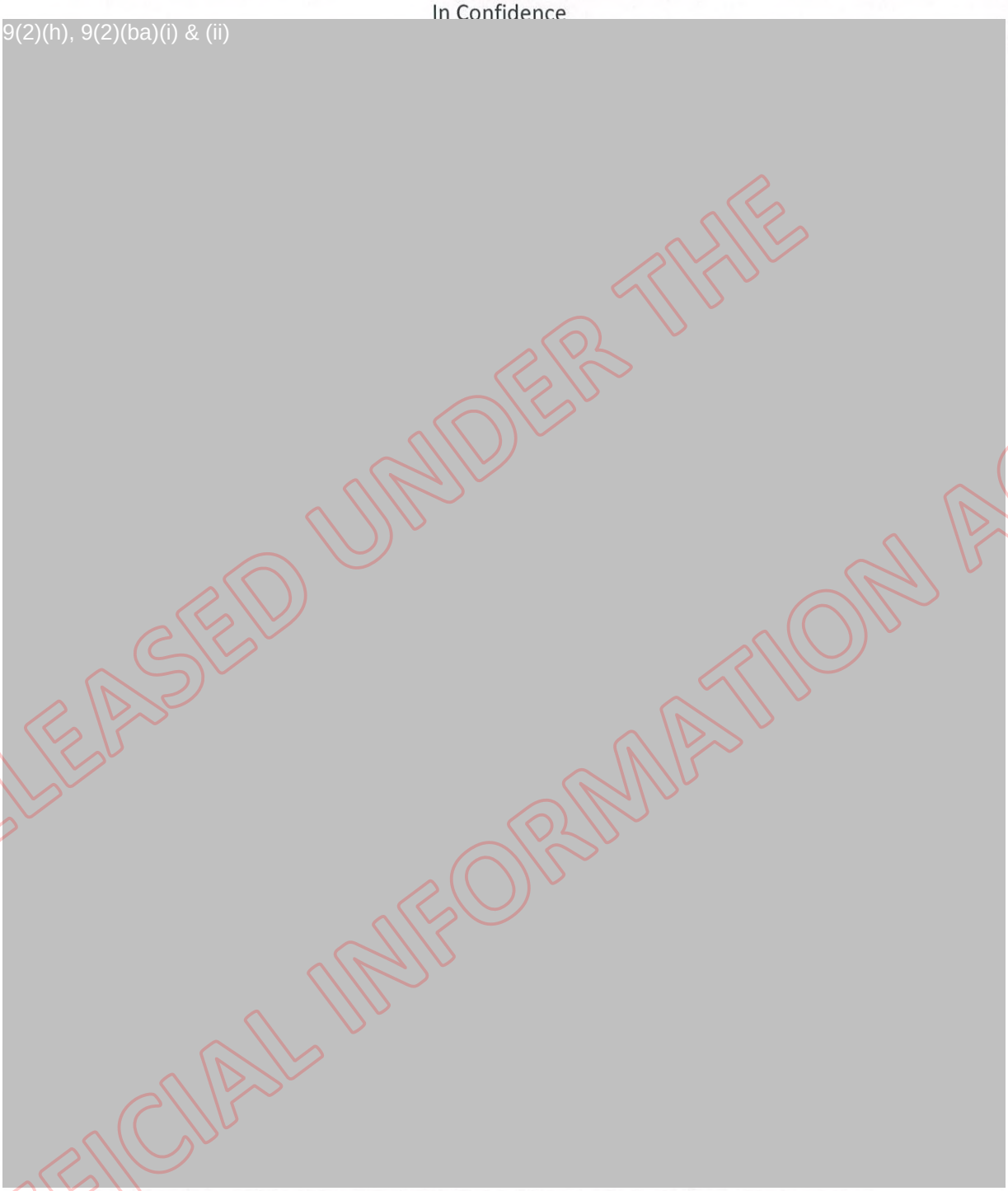
32. Bell Gully has advised that "overall, the risks associated with claims 9(2)(ba)(i) & (ii) which would not be covered by the AC Act seem likely to be relatively low (particularly when assessed against the risks of not accessing a vaccine), with the Crown able to take certain steps to protect its position 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)

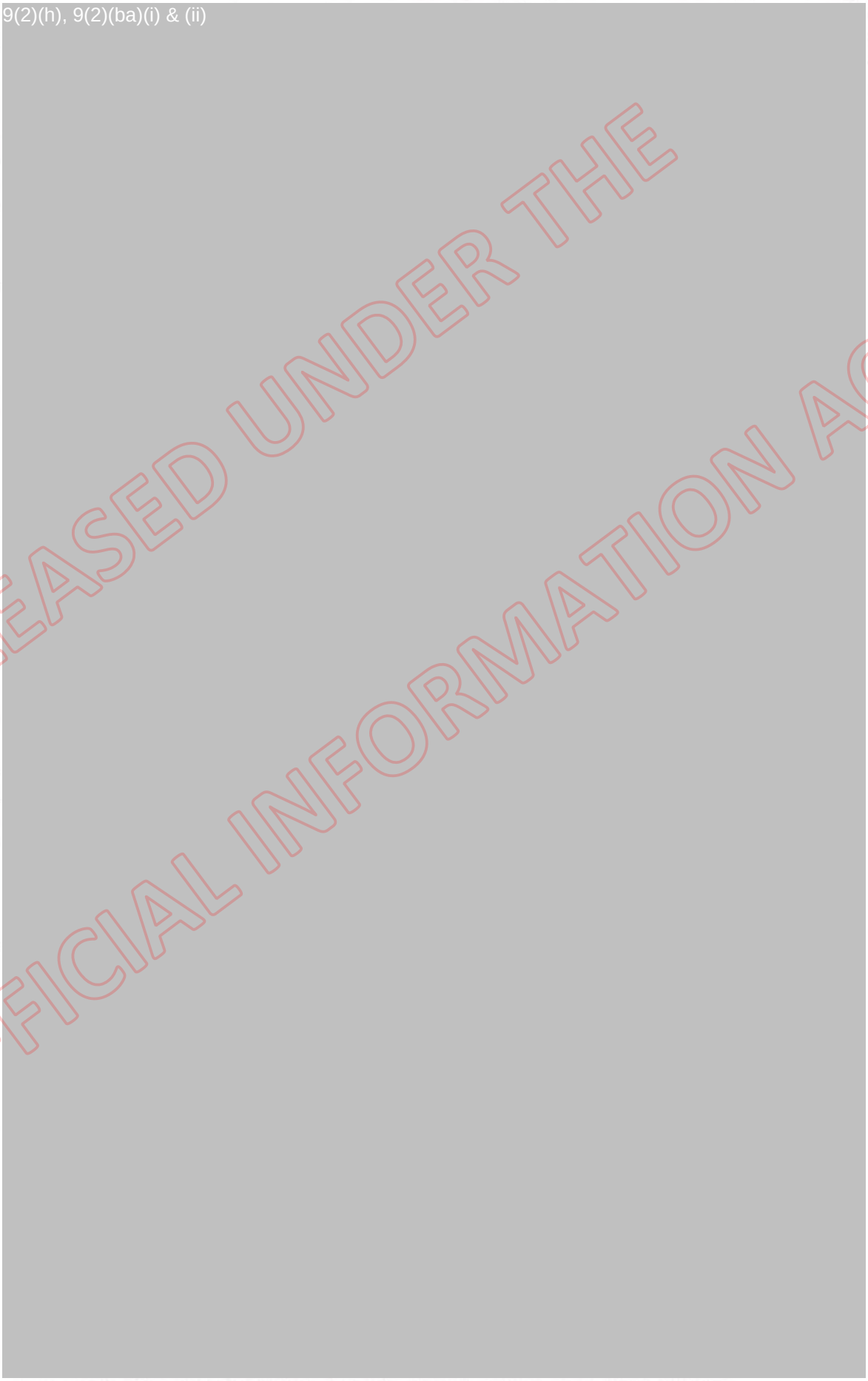
[5] Access to cover depends on the circumstances of the injury – including that there must be a clear causal link between the treatment and the injury, and the injury must not be a necessary part or ordinary consequence of the treatment.



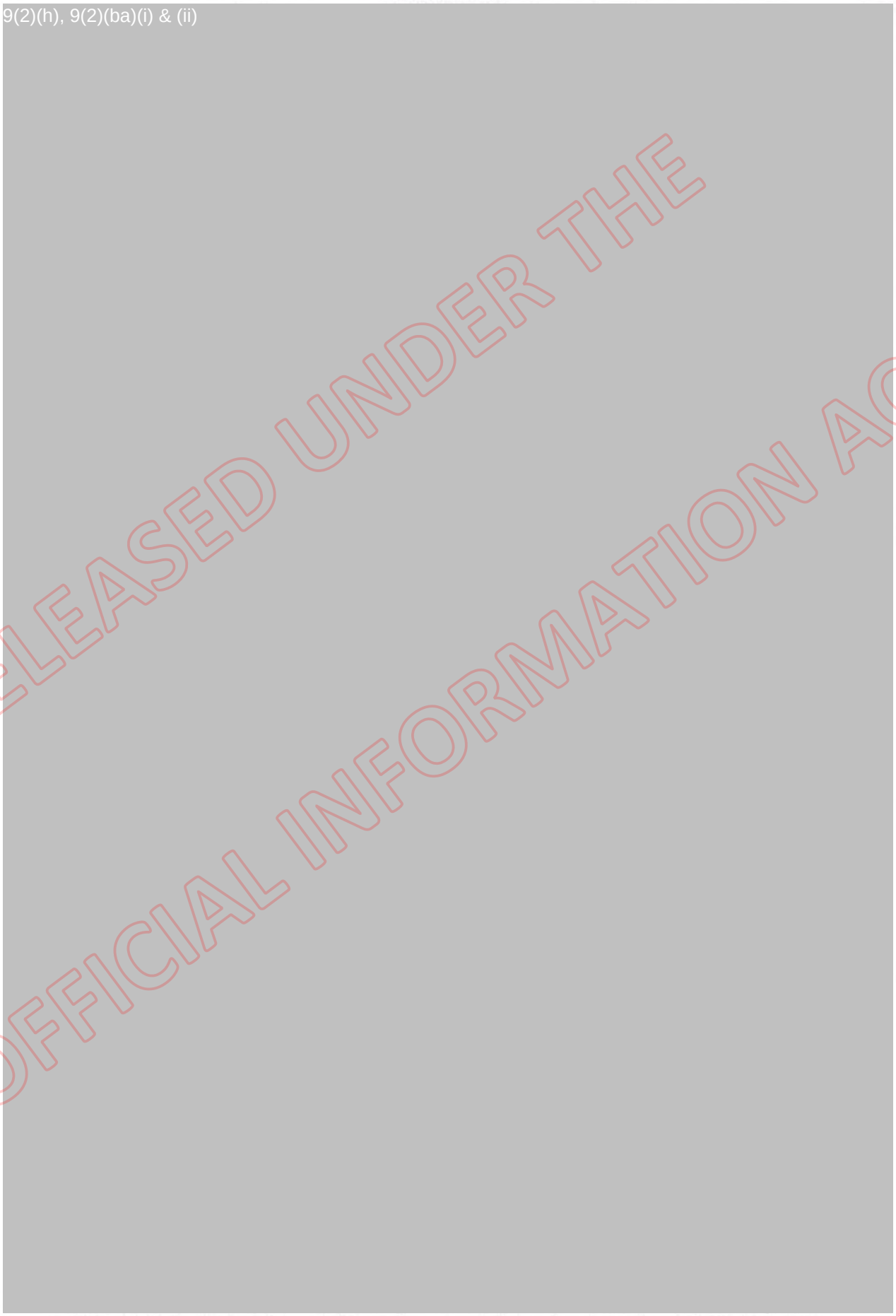
9(2)(h), 9(2)(ba)(i) & (ii)



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



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



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

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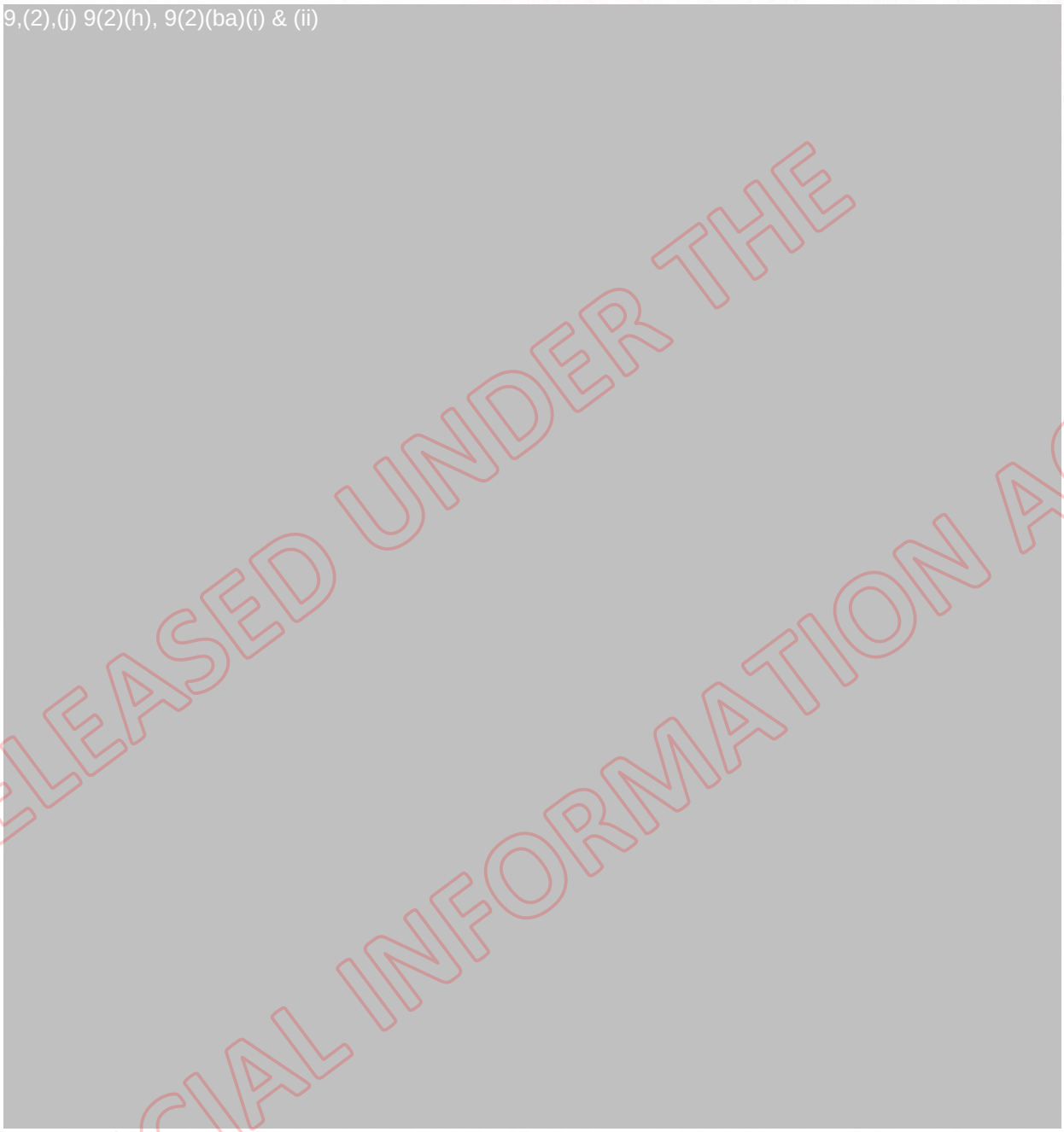
9,(2),(j) 9(2)(h), 9(2)(ba)(i) & (ii)



48. Bell Gully advises that it is not possible at this stage to estimate the maximum potential liability the Crown could incur under the AstraZeneca 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

49. 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.

50. AstraZeneca's status as a well-established company in New Zealand with strong capability to facilitate or support the distribution, tracking and recall of a vaccine

mitigates the risk of treatment injuries associated with use of the vaccine. Other 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 FDA, EMA, TGA) to assess the safety and efficacy of the vaccine.
- 9(2)(ba)(i) & (ii) [redacted]
- 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) [redacted]

We are working to mitigate additional risks associated with the indemnity

51. 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 mitigate the risk of any claims relating to an ineffective vaccine or negligent misstatement.

52. 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.

53. 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 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)

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

Termination Arrangements

61. 9(2)(ba)(i) & (ii)

Necessary or Expedient in the Public Interest

62. The Public Finance Act (PFA) says that the Minister of Finance may give an indemnity if it appears to the Minister to be necessary or expedient in the public interest to do so.

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

63. 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.

64. We judge that the indemnity is in the interest of the New Zealand public because the benefits that the APA can bring to New Zealand (outlined below) outweigh the risks 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 AstraZeneca

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

66. An APA with AstraZeneca will contribute to our portfolio of APAs for promising vaccine candidates.

67. 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.

68. This vaccine could play an important role in the portfolio to provide broad population coverage and be effective for older people:

    a. 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.

    b. Similar to Janssen's vaccine, the AstraZeneca vaccine could offer broad population cover (with a top-up purchase through the COVAX Facility, which we have expressed interest in - briefing MBIE-2021-0858 refers) and is based on replicating viral vector technology. This is one of the three platform types we expect the core portfolio to include.

69. 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.

70. 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.

71. 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

72. 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.

73. 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.

74. 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.

75. 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.

76. 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.

77. 9(2)(ba)(i) & (ii)

78. 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.

79. 9(2)(ba)(i) & (ii) 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).

80. 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.

The indemnity is expedient in the public interest

81. 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".

82. Granting the indemnity in order to conclude an APA with AstraZeneca is expedient because it will help us achieve our Vaccine Strategy objective of securing enough safe and effective vaccines for New Zealand and Polynesia.

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

84. 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% of our population with an uncertain end date for delivery). 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.

85. At this stage our portfolio is still under construction. So far we have one vaccine offering wide population coverage (five million courses of the Janssen vaccine candidate, a viral vector vaccine). An agreement with AstraZeneca would populate the portfolio with a second candidate in sufficient quantities to provide broad population cover (when topped up through a purchase via the COVAX Facility).

86. We might also be able to increase our volume of Pfizer/BioNTech's mRNA vaccine from 750,000 courses to wide coverage levels 9(2)(ba)(i) & (ii)

87. In addition to the above three candidates, the Vaccine Task Force has prioritised concluding an APA for the purchase of a fourth vaccine candidate produced by Novavax by the end of the year. Securing these four APAs will give us a promising 'core portfolio' that is expected to meet the objectives of the Vaccine Strategy.[6]

[6] 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.

88. 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.

89. 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, 9(2)(ba)(i) & (ii) 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.

Overall judgement

90. As for the Pfizer indemnity, Bell Gully has advised that the risks associated with claims 9(2)(ba)(i) & (ii) 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) & (ii)

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

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

93. We judge that in the current circumstances, where New Zealand's ability to recover from the COVID-19 pandemic and relax public health controls relies on obtaining safe and effective vaccines, the benefits of concluding an APA with AstraZeneca outweigh the risks and justify granting the indemnity.

Risk Management

94. 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

95. 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

96. We are briefing responsible Ministers in parallel with submitting the business case to the Treasury, in order to conclude the agreement with AstraZeneca as quickly as possible. AstraZeneca's offer is time-limited, and the purchase agreement needs to be concluded promptly in order to secure the vaccines for New Zealand from a global allocation.

Notification Requirements

97. 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 AstraZeneca in an Advance Purchase Agreement for the supply of AZD1222, a vaccine for the prevention of SARS-CoV-2 in humans.

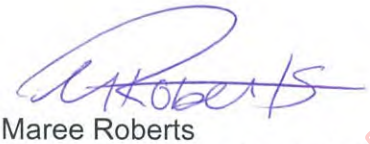
Dated at Wellington this [insert date of month] day of [insert month] [insert year].

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 AstraZeneca on the terms contained in the supply agreement in Annex Onetable.

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