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

Introduction

1. Negotiations have concluded on a definitive advance purchase agreement (APA) for the purchase of vaccines from Janssen Pharmaceutica NV (Janssen).

2. Ministers agreed to non-binding heads of terms forming the basis of this APA in November, and both parties agreed at that time to negotiate a definitive APA within four weeks. The heads of terms demonstrated the parties' intention to conclude a binding agreement but do not constitute a legal obligation on Janssen to supply their vaccine candidate to New Zealand.

3. Janssen has offered New Zealand two million courses of its vaccine candidate (known as Ad26.COV2.S) 9(2)(ba)(i) & (ii) and an option to purchase a further three million courses 9(2)(ba)(i) & (ii). The candidate is an inactivated viral vector vaccine.[1] It will cost 9(2)(ba)(i) & (ii) course which Janssen represents as a non-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)

4. Similarly to the other three priority vaccine candidate suppliers, 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.

5. 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.

6. The terms of Janssen's offer to sell the vaccines to New Zealand are contained in the APA attached as Annex One. The substantive terms of the proposed APA were agreed in the non-binding heads of terms arrangement executed in November. The APA 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.

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

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

[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] 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 9(2)(ba)(i) & (ii) vaccine is 9(2)(ba)(i) & (ii). Five million vaccines costs 9(2)(ba)(i) & (ii) million which would be 9(2)(ba)(i) & (ii) million. There is a foreign exchange risk and the Treasury have recommended including headroom of 9(2)(ba)(i) & (ii) million to address that risk. Therefore the amount required to be set aside for the purchase is 9(2)(ba)(i) & (ii) million.

8. Officials are not recommending exercising the option to purchase the additional three million courses at this stage because further relevant information may become available before this decision is necessary. 9(2)(ba)(i) & (ii)

9. Officials believe there is a strong rationale to sign the APA because:

   a. 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.[3] 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.

   b. Janssen, along with its parent company Johnson & Johnson, 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.

   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 and the EU have advance purchase arrangements with Janssen for around 570 million courses of this vaccine candidate.[4] Those countries have used similar frameworks to ours, using their experts to interrogate the early science results, trial designs and manufacturing programmes.

   e. The Janssen candidate will populate the portfolio with a viral vector vaccine that offers broad population cover (we have 3.8 million courses of the other viral vector candidate in the portfolio – the AstraZeneca candidate – which we are seeking to top up through the COVAX Facility).

   f. 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.

10. 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.

11. As part of the APA, Janssen is seeking an indemnity from the Crown 9(2)(ba)(i) & (ii) The indemnity will only apply to the extent loss is not covered, or claims are not barred, by the Accident Compensation Act (AC Act). 9(2)(ba)(i) & (ii)

12. Janssen are seeking the indemnity because:

[3] 9(2)(ba)(i) & (ii)

[4] 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.

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; [5] and

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

13. 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.

14. The business case incorporates the information and advice from our external legal advisers that we provided to the Treasury about the indemnity in November (attached at Annex Two), with two key updates:

- An assessment of the indemnity-like obligations in the agreement
- A comparison of the indemnity with indemnities negotiated with AstraZeneca and Novavax as well as Pfizer.

Background

15. 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.

16. As part of purchase agreements for COVID-19 vaccines, the Minister of Finance granted indemnities in favour of Pfizer/BioNTech on 5 October, Novavax on 15 December and AstraZeneca on 15 December.

17. 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

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

[redacted]

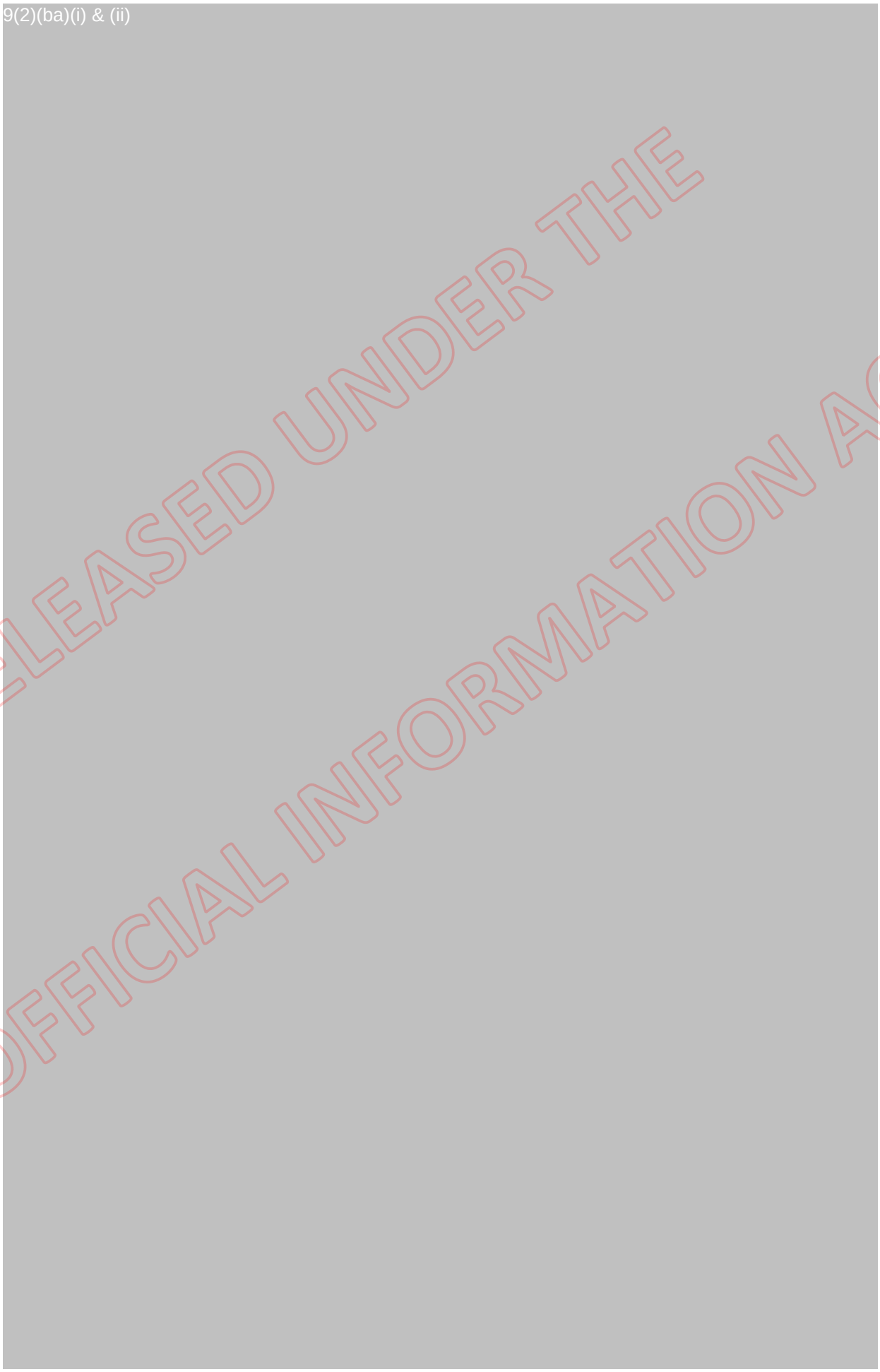
[5] Janssen will provide Medsafe with full clinical trials information when they apply for regulatory approval. Study designs and regulatory approaches will vary between COVID-19 vaccine applicants, but most trials will be shorter in length and study fewer people than what is typical. The impact is a 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)

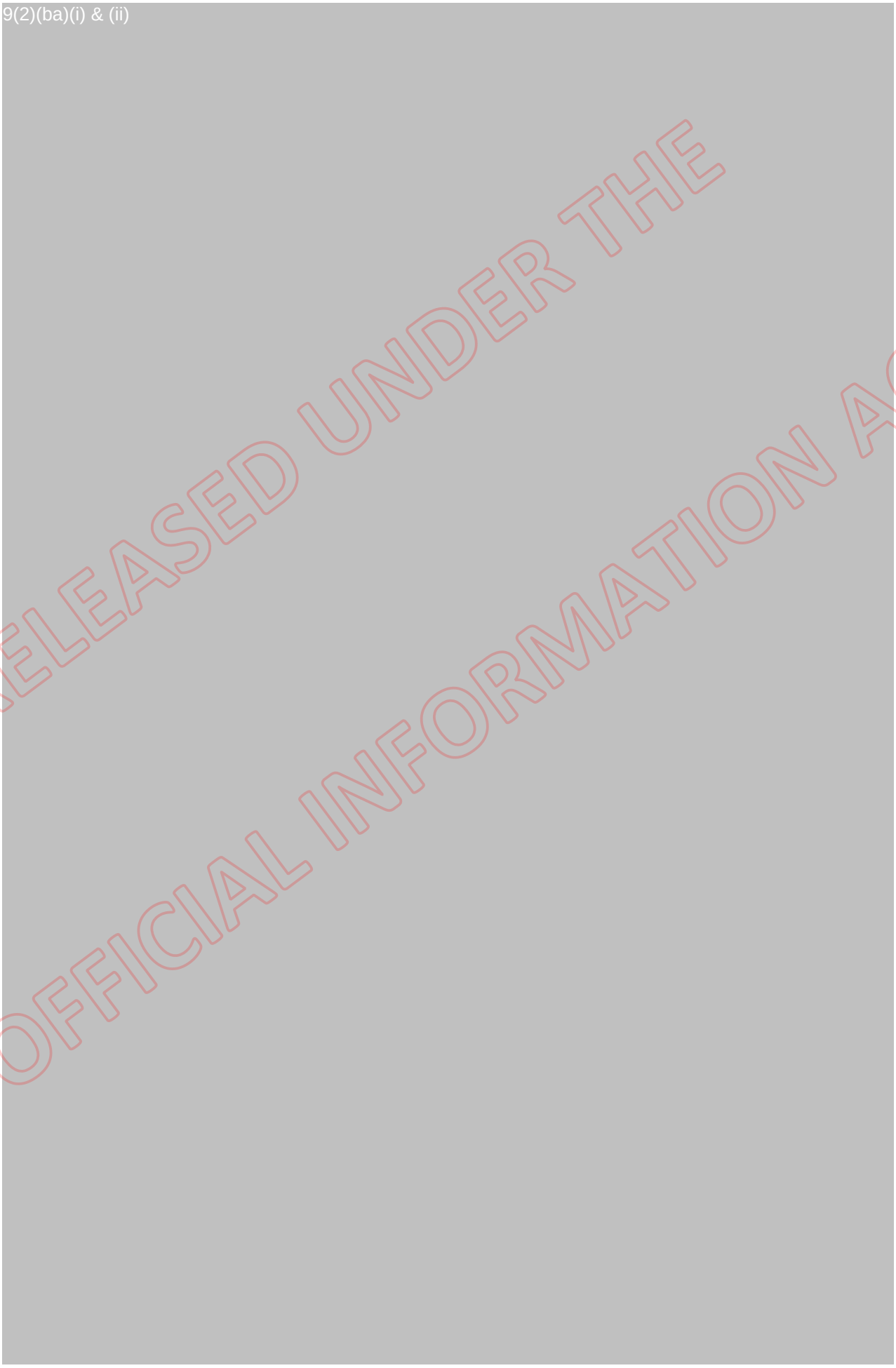
Scope of the indemnity

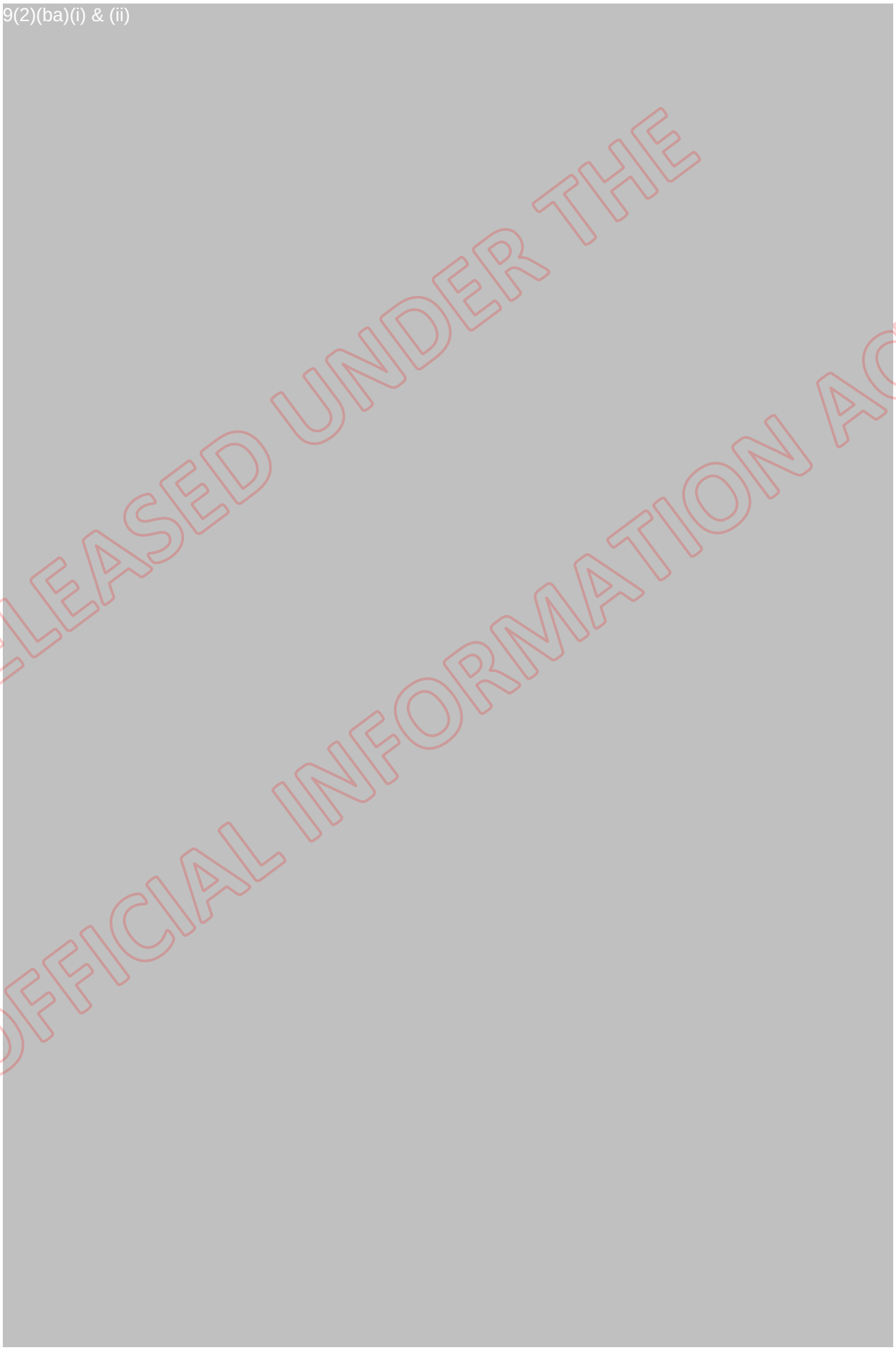
9(2)(ba)(i) & (ii)

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



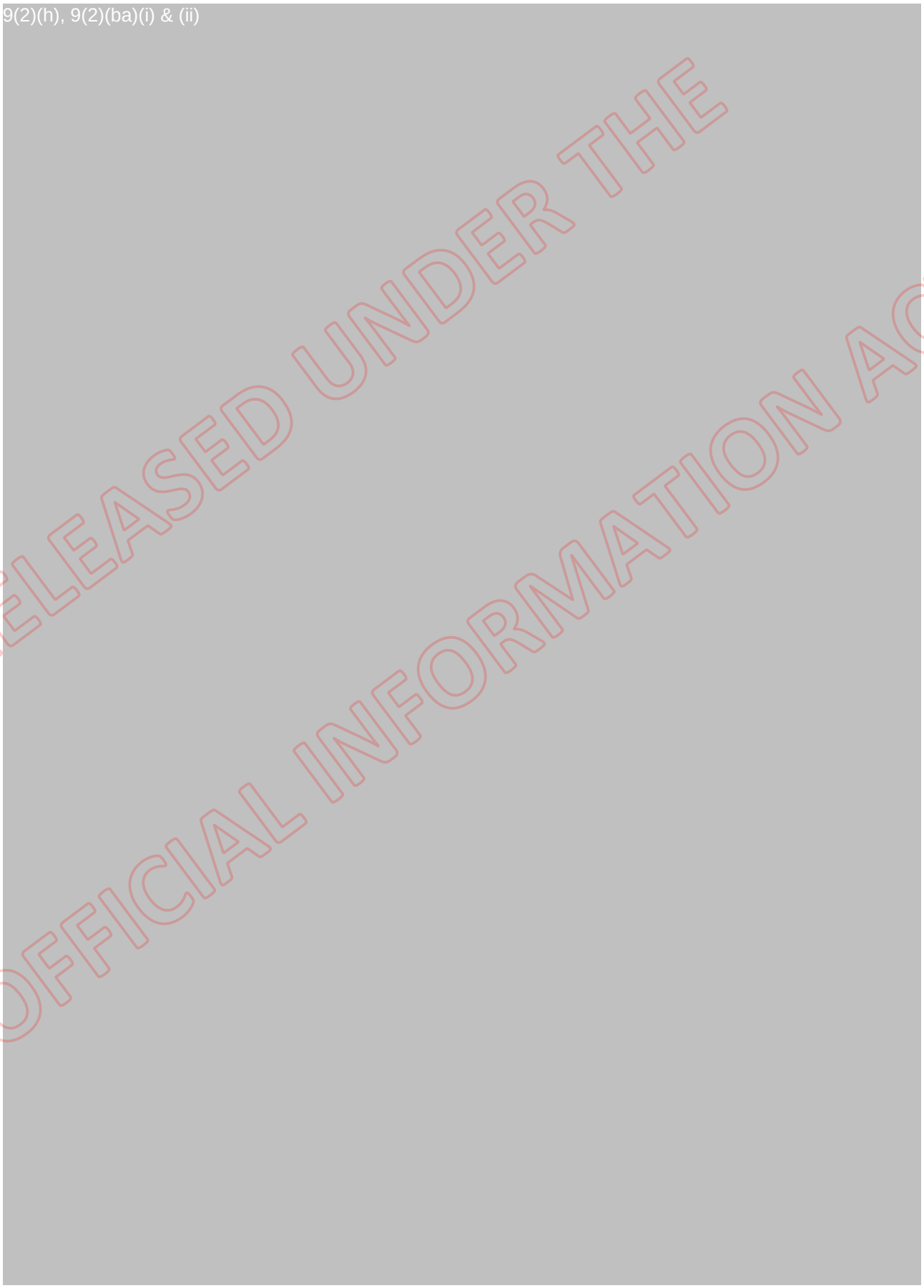
9(2)(ba)(i) & (ii)



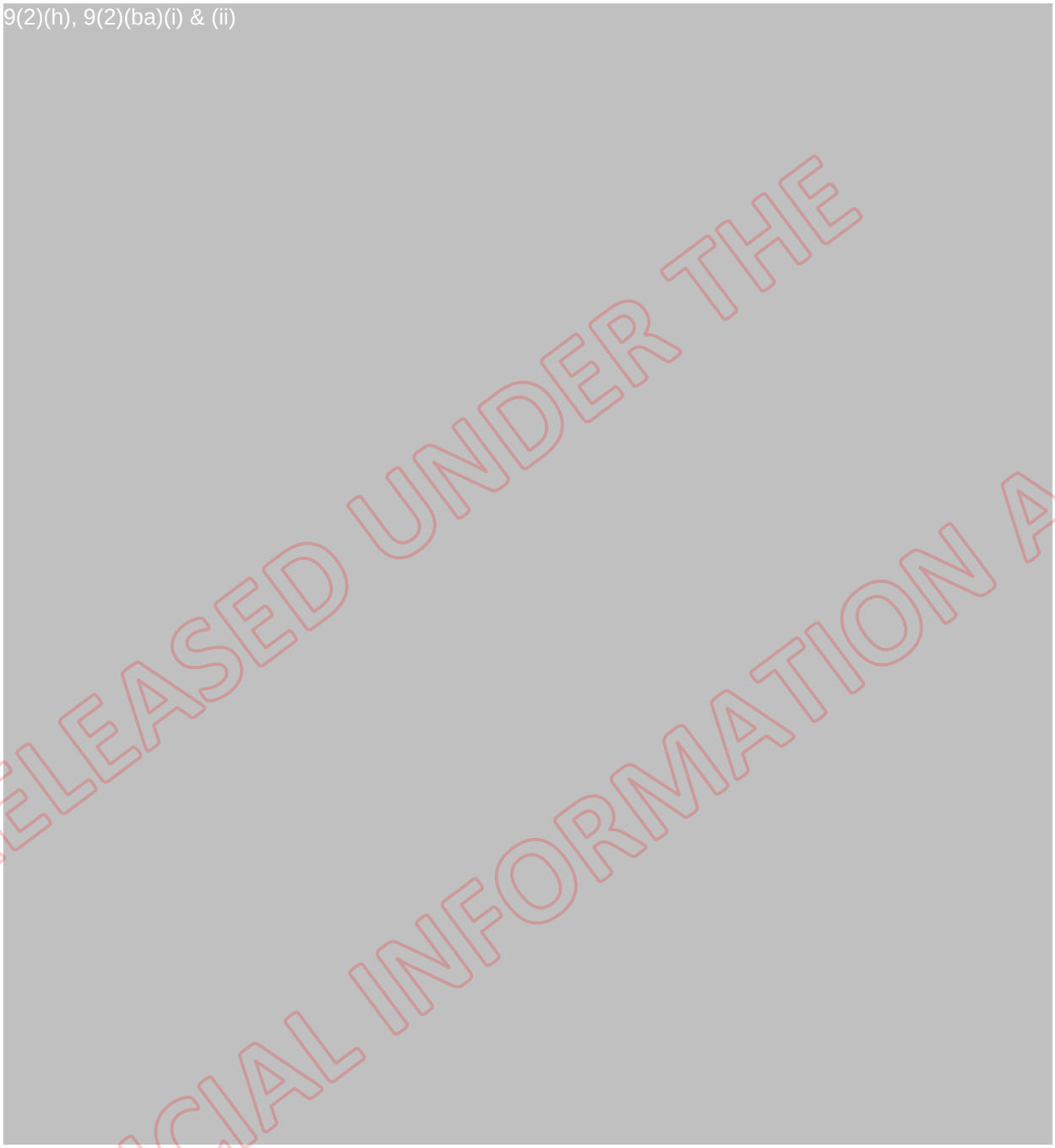


24. Bell Gully has provided the following explanation of the provisions:

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



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



31. A table comparing the Janssen, Pfizer, AstraZeneca and Novavax indemnities is attached at Annex Three."

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

Exposure, risk and mitigation

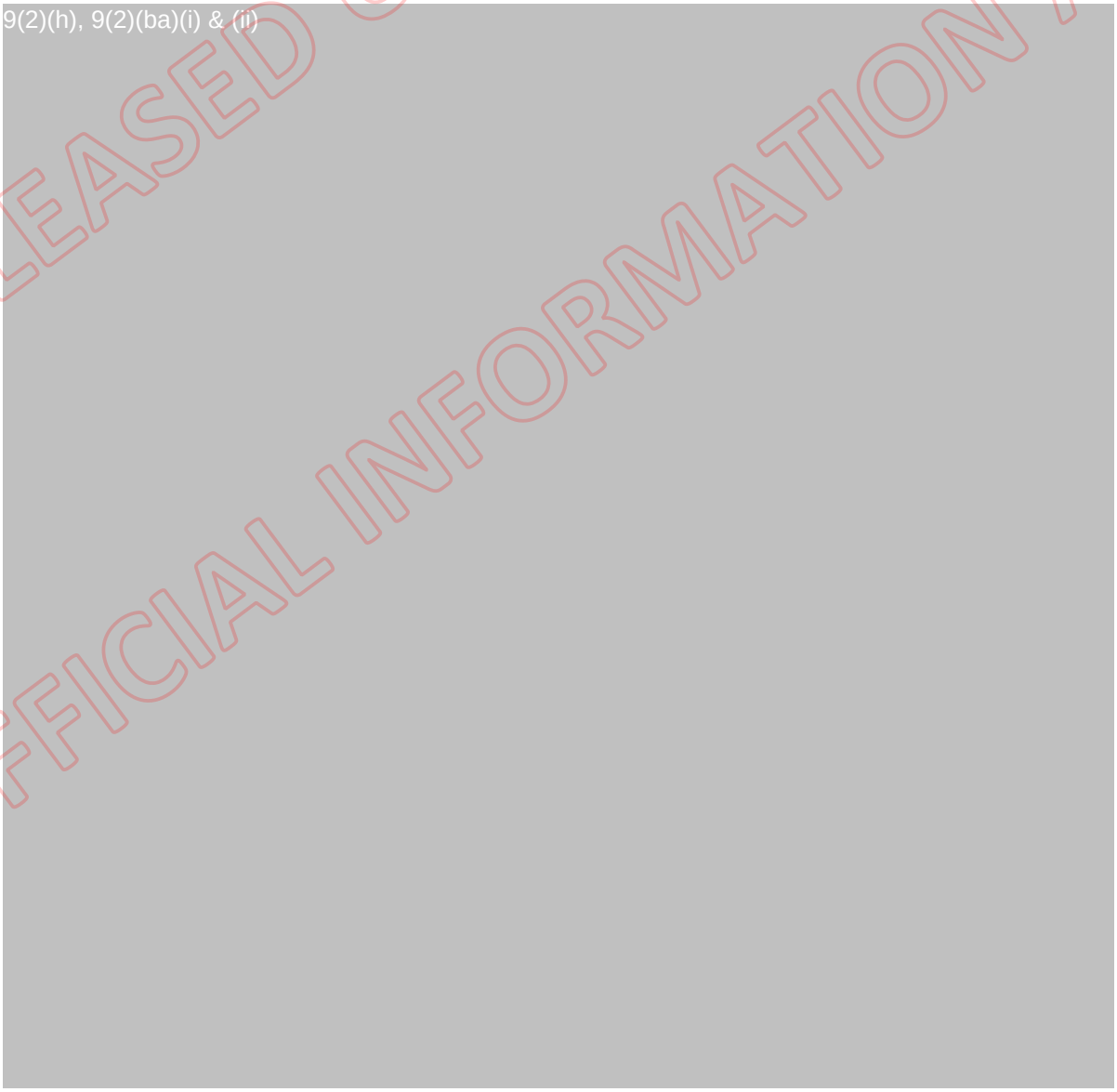
ACC will cover most of the Crown's liability for adverse effects associated with use of the vaccine

33. 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.

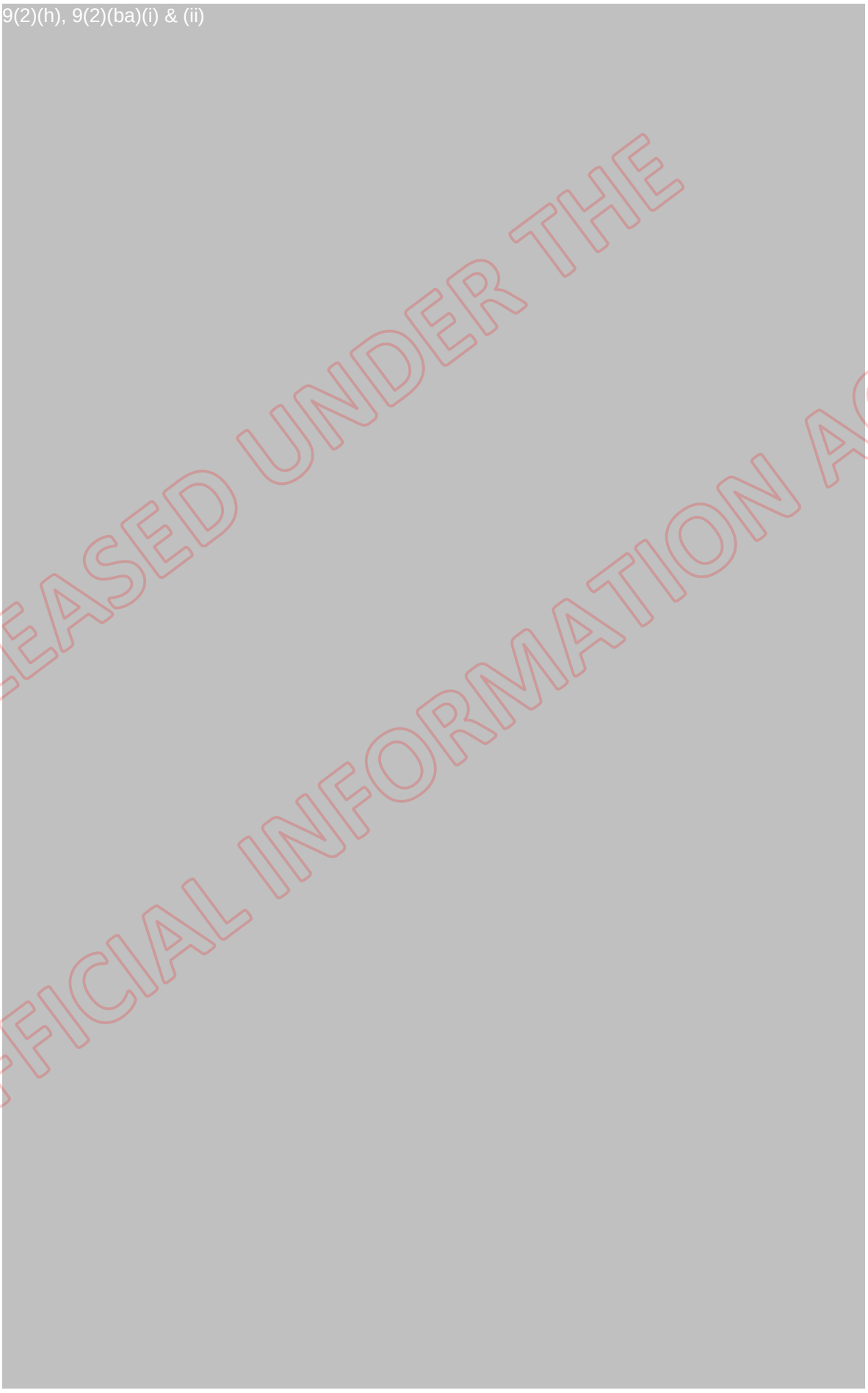
The liability associated with claims not covered by ACC is relatively low-risk

34. Bell Gully has advised that "[o]verall, the risks associated with claims 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.

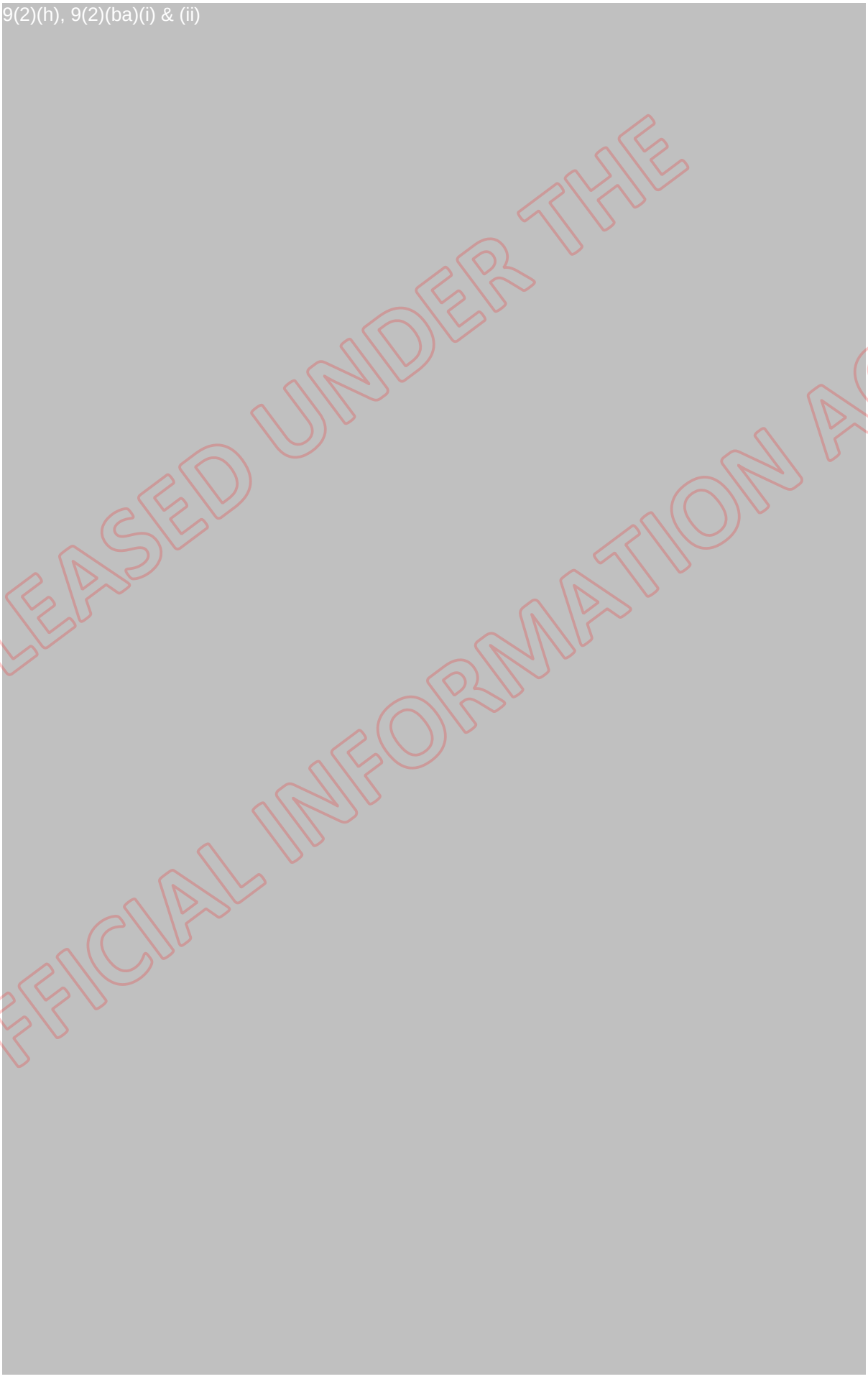
9(2)(h), 9(2)(ba)(i) & (ii)

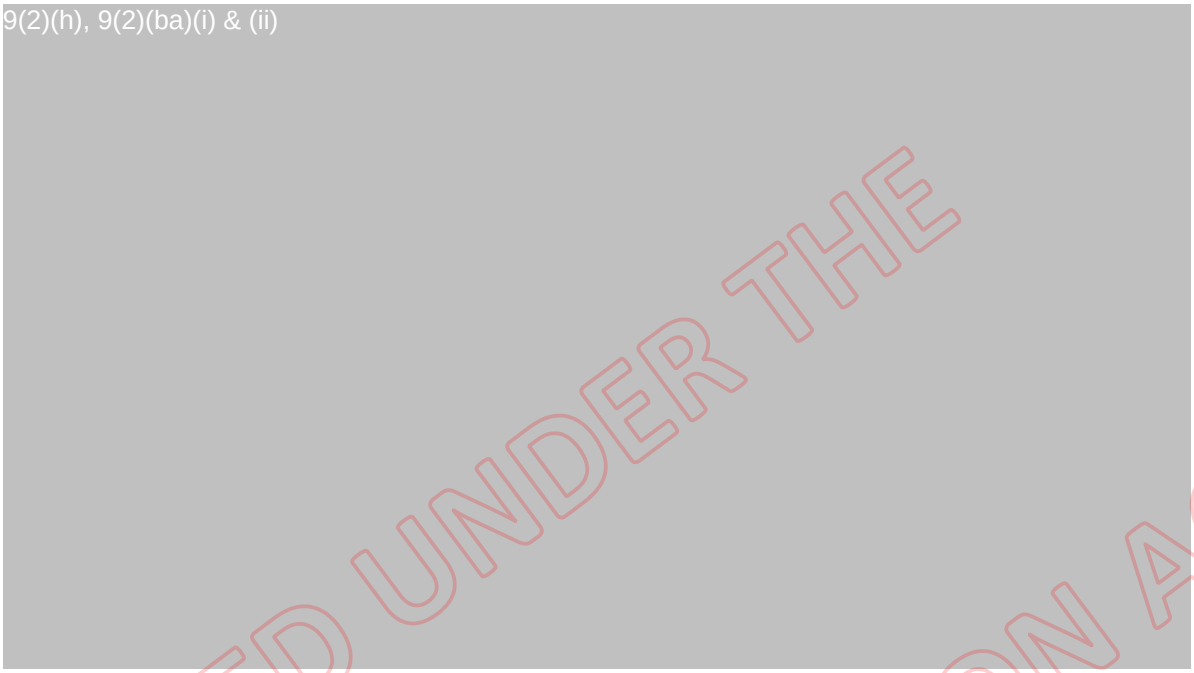


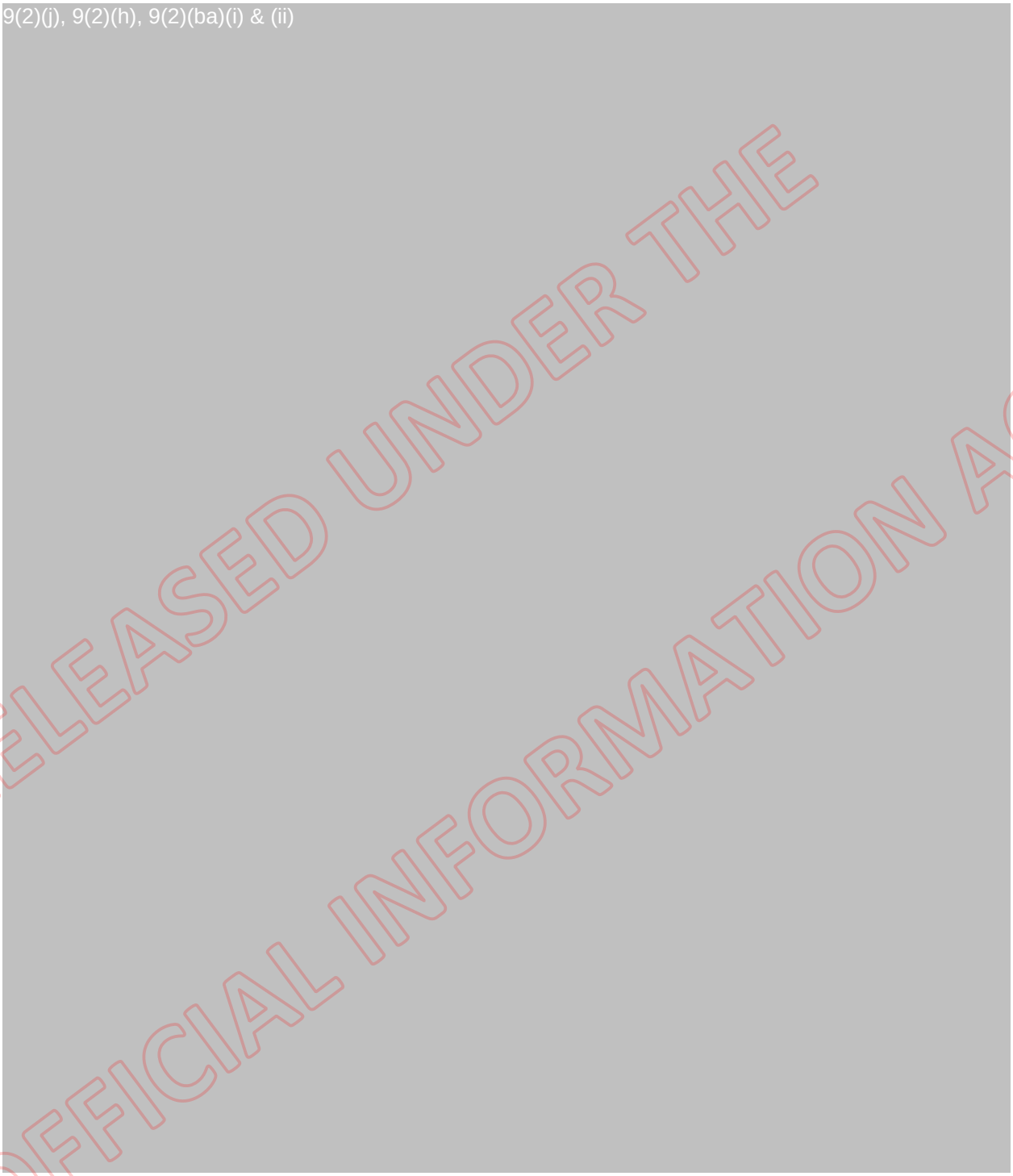
[6] Access to cover depends on the circumstances of the injury – including that there must be a clear causal link between the treatment and the injury, and the injury must not be a necessary part or ordinary consequence of the treatment.



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







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

45. 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)

9(2)(ba)(i) & (ii) – though as noted above, Bell Gully considers these risks to be relatively low.

46. Janssen's (and its parent company Johnson and Johnson's) very strong track record in producing safe and efficacious pharmaceutical products for use globally and in New Zealand, and associated 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 (e.g. FDA, EMA, TGA) to assess the safety and efficacy of the Janssen 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

47. 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 of our stakeholder and public communication. This will help to mitigate the risk of any claims relating to an ineffective vaccine or negligent misstatement.

48. 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.

49. 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" and such

statements have already been tabled in relation to the Pfizer indemnity and our involvement with the COVAX Facility).

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

[redacted]

that is relevant to the decision under the authorising provisions in the Medicines Act.

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

[redacted]

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

Termination Arrangements

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

Necessary or Expedient in the Public Interest

59. 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

60. 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.

61. 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 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 Janssen

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

63. An APA with Janssen will contribute to our portfolio of APAs for promising vaccine candidates.

64. 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.

65. 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 and available in sufficient quantities to provide wide population cover within the timeframes required to implement the immunisation programme.

66. The 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.

67. 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 of these viral vector candidates.

68. 9(2)(ba)(i) & (ii) 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.

69. 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.

70. 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

71. 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, and restrictions on movement) are designed to do.

72. 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.

73. 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.

74. 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.

75. 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.

76. 9(2)(ba)(i) & (ii)

77. 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.

78. Earlier this month, Cabinet agreed that up to $75 million be allocated from Vote Official Development Assistance to support Pacific and global access to COVID-19 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].

79. 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 Janssen is expedient in the public interest

80. 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”.

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

82. 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.

83. 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 (e.g. 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.

84. At this stage our portfolio is still under construction. So far we have:

- 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), and
- 5.36 million courses of the Novavax candidate, a protein sub-unit and adjuvant vaccine.

85. Concluding the APA with Janssen is critical to securing a 'corner-stone' vaccine in our portfolio: a potentially single-dose vaccine offering wide population cover.

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

87. 9(2)(ba)(i) & (ii) This increases the importance of securing Janssen's vaccine for our portfolio. 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.

82. We will also investigate the purchase of another wide-coverage candidate and continue to consider smaller purchases, including through the COVAX Facility.

88. Not purchasing the Janssen candidate would have the following implications for the portfolio:

- 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 Janssen vaccine candidate was not pursued, the portfolio would only have two vaccine candidates that can offer wide population coverage. It may still have one candidate from each of the three main platforms we are targeting, but there would be reduced optionality for the immunisation programme when deciding what vaccines to deploy and when.

Overall Judgement

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

90. Bell Gully has advised that:

- 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**, with the Crown able to take certain steps to protect its position as far as possible.

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

Risk Management

91. 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

92. 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

We are briefing responsible Ministers in parallel with submitting the business case to the Treasury, in order to conclude the agreement with Janssen as quickly as possible. The APA needs to be executed without delay to secure access to the available Janssen vaccines.

Notification Requirements

93. 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 Janssen Pharmaceutica NV and specified associated persons in relation to the supply of a COVID-19 vaccine.

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 Janssen Pharmaceutica NV on the terms outlined 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: information provided to the Treasury in November 2020

Annex Three: indemnities comparison (supplied by Bell Gully)

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

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

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