MINISTRY OF BUSINESS, INNOVATION & EMPLOYMENT
HĪKINA WHAKATUTUKI

COVID-19 Vaccine Strategy Task Force

TERMS OF REFERENCE

PURPOSE

The role of the COVID-19 Vaccine Strategy Task Force is to set direction, drive action at pace, coordinate activity, and monitor progress by agencies in support of the COVID-19 Vaccine Strategy approved by Cabinet. It will also coordinate advice and information to the Minister of Research, Science and Innovation, the Minister of Health, and the Minister of Foreign Affairs on its further elaboration and ongoing implementation.

This will ensure that:

- Agencies have a shared understanding of the operating context, and the issues and priorities for New Zealand
- The Strategy is further developed as new information becomes available or if the situation changes
- Agency activity in support of the Strategy is effectively coordinated and aligned
- Advice provided to Ministers and Cabinet is informed by a full range of views, and that the trade-offs as well as the wider synergies are clearly identified in a holistic manner
- Critical actions for the success of the strategy are clearly allocated to an owner, actioned and followed up
- Agencies have a shared process for monitoring progress and risk to inform adjustments to the strategy itself, as well as agency work plans.

The goal of the Task Force is for agencies to operate a single all of government team to implement the strategy.

SCOPE

The COVID-19 Vaccine Strategy Task Force will be responsible for coordinating activity in support of the Government's COVID-19 Vaccine Strategy, and leading on the provision of advice to Ministers and Cabinet in relation to this.

The Task Force may also be called on to provide feedback or to support other areas where relevant and when requested by joint Ministers or by Cabinet.

MEMBERSHIP

- Dr Peter Crabtree, General Manager Science, Innovation, and International, Ministry of Business, Innovation and Employment (Chair)
- Dr Prue Williams, General Manager, Science System Investment and Performance, Ministry of Business Innovation and Employment
- Dr Ian Town, Chief Science Advisor, Ministry of Health (Chair of Science Advisory Board)
- Prof David Murdoch, Science and Technology Advisory Group
- Maree Roberts, Deputy Director-General System Strategy and Policy, Ministry of Health
- Chris James, General Manager Medsafe, Ministry of Health
- Lisa Williams, Director of Operations, PHARMAC
- David Taylor, Divisional Manager, Covid Policy and Coordination Division, Ministry Foreign Affairs and Trade
- Cheryl Barnes, National Crisis Management Centre COVID-19 Response, Department of the Prime Minister and Cabinet
- Dr James Ussher, science leader of the vaccine research platform (Vaccine Alliance Aotearoa New Zealand)
- John Whaanga, Māori Health representative, Ministry of Health
- Mark Vink, Acting Director, COVID Economic Response Directorate, Treasury
- Melody Guy, Acting Director, COVID Economic Response Directorate, Treasury

The Task Force can choose to co-opt members if it considers that it requires access to expertise that it is not readily available, or invite experts to attend in order to support a particular discussion.

RESPONSIBILITIES

Members of the Task Force will be responsible for representing their agencies, communicating the Task Force's decisions and implications back to these agencies, and ensuring that commitments and agreed actions are undertaken.

It is the responsibility of each Task Force member to engage across their agency in order to represent their views in the task force and to be able to commit their agency to actions agreed by the task force.

ACCOUNTABILITIES

The COVID-19 Vaccine Strategy Task Force's accountabilities are to:

- The Chief Executives of the Ministry of Business, Innovation and Employment, the Ministry of

Health, and the Ministry of Foreign Affairs and Trade, and through them to

- The Minster of Research, Science and Innovation, the Minister of Health, and the Minister of Foreign Affairs and Trade

DECISION RIGHTS

The COVID-19 Vaccine Strategy Task Force does not supersede internal agency accountabilities, and therefore takes decisions by consensus. If agreement cannot be reached, decisions can be escalated to Ministers, and ultimately Cabinet. In keeping with good inter-agency practice, however, this should be seen as a last resort.

OPERATION

Frequency of meetings

The COVID-19 Vaccine Strategy Task Force will meet every fortnight.

The Task Force may be asked to meet on an ad hoc basis outside of the agreed meeting rhythm.

Role of the Chair

The Chair will provide overall leadership of the strategy, and work to ensure agreed positions are reached wherever possible.

Quorum

Quorum will be a majority of Task Force members (half the committee members plus one).

It is expected that named members will attend to represent their agency whenever possible. Where a member is unable to attend, they may nominate someone acting in their position to attend on their behalf so long as that person still has the ability to commit the agency to action as set out in responsibilities above.

Conflicts of Interest

Members should be aware of all actual, perceived and potential conflicts of interest and notify the Chair prior to any meeting. The Secretariat will maintain a register of notified conflicts.

Reporting

The COVID-19 Vaccine Strategy Task Force will report through joint Ministers to Cabinet as required by Cabinet decisions.

Meeting minutes

The Chair will review minutes prior to circulation for endorsement by the Task Force at the following meeting.

Action items will be recorded for all meetings and distributed to Task Force members by the Secretariat.

Secretariat

MBIE will provide the Secretariat. It is the Secretariat's responsibility to:

- Ensure meeting packs are created and promulgated to the committee within an appropriate timeframe agreed by the Task Force.

- Liaise with the Chair and key stakeholders regarding materials being submitted to the Task Force.
- Ensure meeting rooms, teleconference, or video conference units are booked.
- Provide draft minutes to the Chair as soon as possible after a Task Force meeting, and ensure that actions are being followed up in accordance with the agreed due dates.

COVID-19 Vaccine Strategy Science and Technical Advisory Group

TERMS OF REFERENCE

PURPOSE

The role of the COVID-19 Vaccine Strategy Science and Technical Advisory Group (STAG) is to provide scientific and technical advice on vaccine development, manufacturing, and safety to the COVID-19 Vaccine Strategy Taskforce. The Chair and at least one other member of the Advisory Group will be represented on the Taskforce to represent its views.

This will ensure that:

- The direction of the strategy is consistently informed by up to date scientific and technical information
- The strategy is executed within a broad understanding of the scientific and technical context as it applies to New Zealand, including capturing a range of scientific perspectives
- The Taskforce has access to its own source of scientific advice when it is required

SCOPE

The COVID-19 Vaccine Strategy Science and Technical Advisory Group will be responsible for providing scientific and technical advice to the COVID-19 Vaccine Strategy Taskforce on the development, manufacturing of vaccines, and to assist in making judgments about likely safety and effectiveness while vaccine candidates are in development and full safety information is unavailable.

The Science and Technical Advisory Group may also be called on to answer specific questions at the request of the Taskforce that would benefit from its expertise.

The Science and Technical Advisory Group does not substitute for established scientific advice processes that serve the needs of individual agencies represented on the Taskforce, and when formal agency processes require advice from a standing advisory group, the agency group's scientific advice should be seen to prevail in accordance with the agency's formal processes.

When the Taskforce considers it more appropriate it may request advice from specific agency advisory groups, with the agreement of the responsible agency.

Agency representatives on the Taskforce are also entitled to draw on their own scientific advisory groups to support their participation in the Taskforce, and to add to our contest any advice provided by the Science and Technical Advisory Group.

MEMBERSHIP

- Ian Town (Ministry of Health, Chair)*
- David Murdoch (University of Otago Christchurch, Deputy Chair)*
- Sue Crengle (University of Otago)
- Ian Frazer (University of Queensland)
- Matire Harwood (Auckland University)*
- Graeme Jarvis (Medicines NZ)
- Peter McIntyre (University of Otago)*
- Nikki Moreland (Auckland University)*
- Helen Petousis-Harris (Auckland University)*
- John Taylor (Auckland University)
- Nikki Turner (Auckland University)*
- James Ussher (University of Otago)

A Scientific and Clinical Review Panel has also been established as a Sub-Committee of the STAG, convened by the STAG Deputy Chair. The role of this Sub-Committee is to provide advice to the Taskforce on the scientific and clinical merits of Covid-19 vaccine candidates assessed as part of New Zealand's Advance Purchasing Agreement programme or via the international COVAX Facility.

Members of the Scientific and Clinical Review Panel are marked with an asterisk in the membership list above.

RESPONSIBILITIES

Members of the Science and Technical Advisory Group serve in their individual capacity as experts. They are responsible for presenting their views as objectively as possible and contributing their perspectives to advice provided to the Taskforce. Members are expected to weigh the views of other members in supporting the chair to provide the best possible advice to the Task Force.

ACCOUNTABILITIES

The COVID-19 Vaccine Strategy Science and Technical Advisory Group's accountabilities are to:

- Provide advice to the COVID-19 Vaccine Strategy Taskforce as requested by the Taskforce.

DECISION RIGHTS

The COVID-19 Vaccine Strategy Science and Technical Advisory Group does not take decisions.

The Science and Technical Advisory Group is not expected to reach consensus, and the Chair may present its advice as a range of views.

OPERATION

Frequency of meetings

The COVID-19 Vaccine Strategy Science and Technical Advisory Group will meet monthly or at the request of the Taskforce.

The Science and Technical Advisory Group may be asked to meet on an ad hoc basis outside of the agreed meeting rhythm.

Role of the Chair

The Chair of the Taskforce is responsible for summarising advice for the Taskforce, including in accurately reflecting the range of views expressed and fairly representing any disagreements on technical issues.

Quorum

Quorum will be a majority of Science and Technical Advisory Group members (half the committee members plus one).

Because members serve in their individual capacity there are no substitutes.

Conflicts of Interest

Members should be aware of all actual, perceived and potential conflicts of interest and notify the Chair prior to any meeting. The Secretariat will maintain a register of notified conflicts.

Fees and expenses

Payment of fees and expenses incurred will be made to STAG members for attendance at and preparation for STAG meetings. This includes activities relating to the Scientific and Clinical Review Panel for eligible STAG members.

In line with the State Services Commission guidance on payment, a maximum daily fee of $865 is available for members attending meetings, including preparation. For members acting in Chair and Convenor roles, a maximum daily fee of $1150 is available. No fees will be paid for any STAG member employed by a public sector department.

These rates will be applied on a pro-rata basis for number of hours worked. Payment will be made on an hourly basis for all time spent at meetings, plus one hour of preparation/follow up time for every two hours of meeting time.

Expenses for participation will be reimbursed for out-of-pocket travel, meals, and accommodation actually and reasonably incurred.

Any additional work carried out by members, beyond attendance, preparation and follow-up to meetings, should be approved by the Chair, before being carried out.

Reporting

The COVID-19 Vaccine Strategy Science and Technical Advisory Group will report to the Taskforce

through its Chair.

Meeting minutes

The Chair will review minutes prior to circulation for endorsement by the Science and Technical Advisory Group at the following meeting.

Secretariat

MBIE will provide the Secretariat. It is the Secretariat's responsibility to:

- Ensure meeting packs are created and promulgated to the committee within an appropriate timeframe agreed by the Science and Technical Advisory Group.
- Liaise with the Chair and key stakeholders regarding materials being submitted to the Science and Technical Advisory Group.
- Ensure meeting rooms, teleconference, or video conference units are booked.
- Provide draft minutes to the Chair as soon as possible after a Science and Technical Advisory Group meeting, and ensure that actions are being followed up in accordance with the agreed due dates.

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 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.

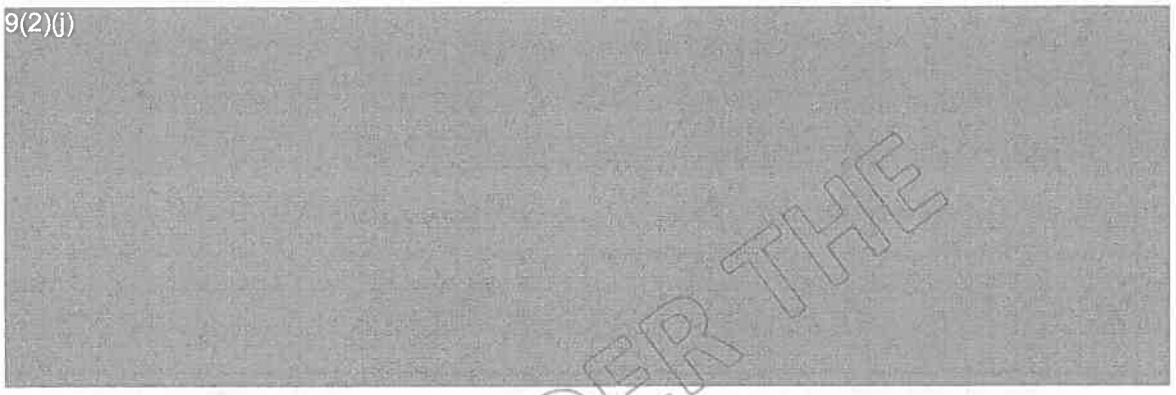
Our aim in negotiations on indemnity is to minimise the Crown's liability

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

[redacted]

[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)



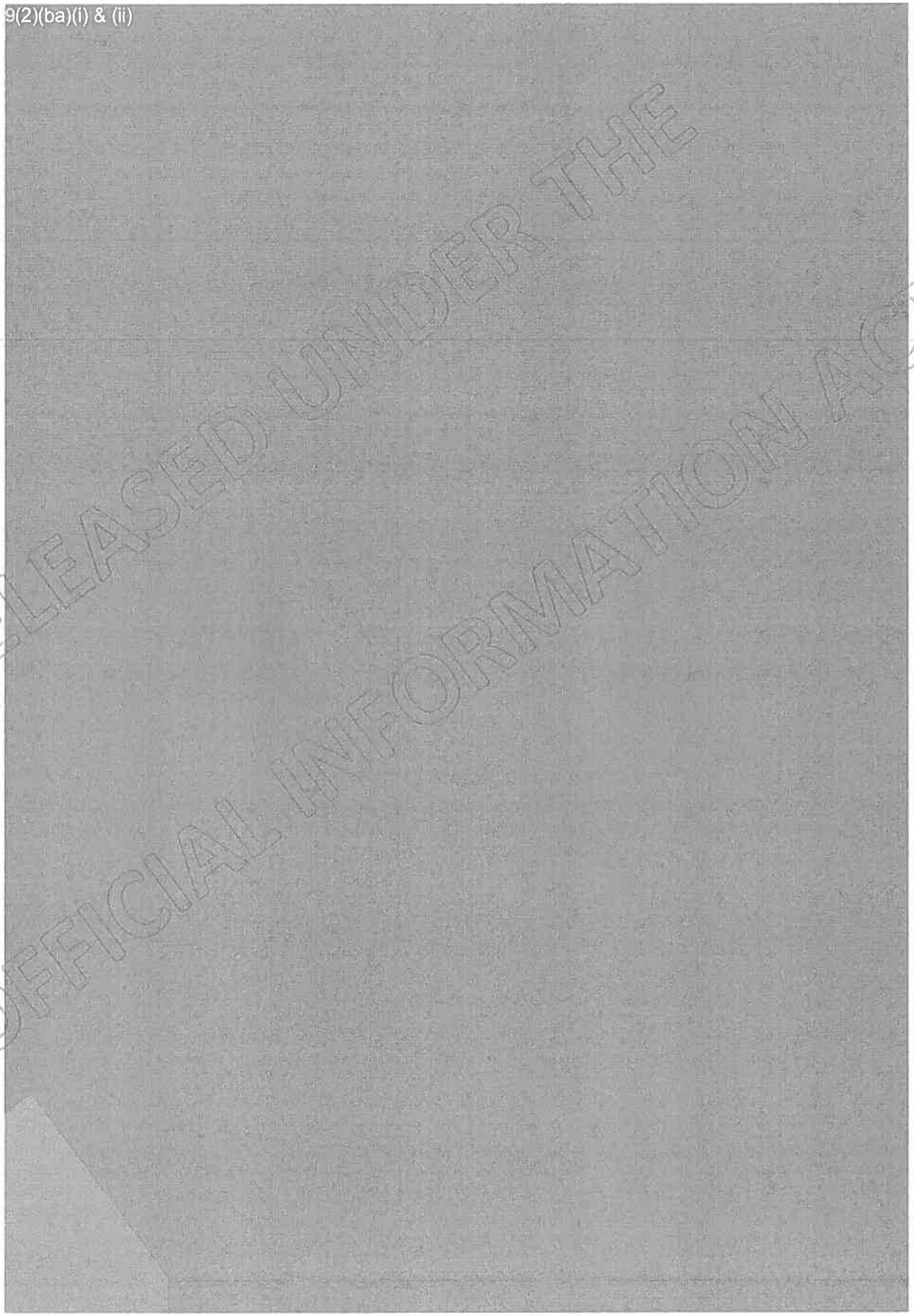
Scope of the indemnity

19. The indemnity reads:

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

[redacted]

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



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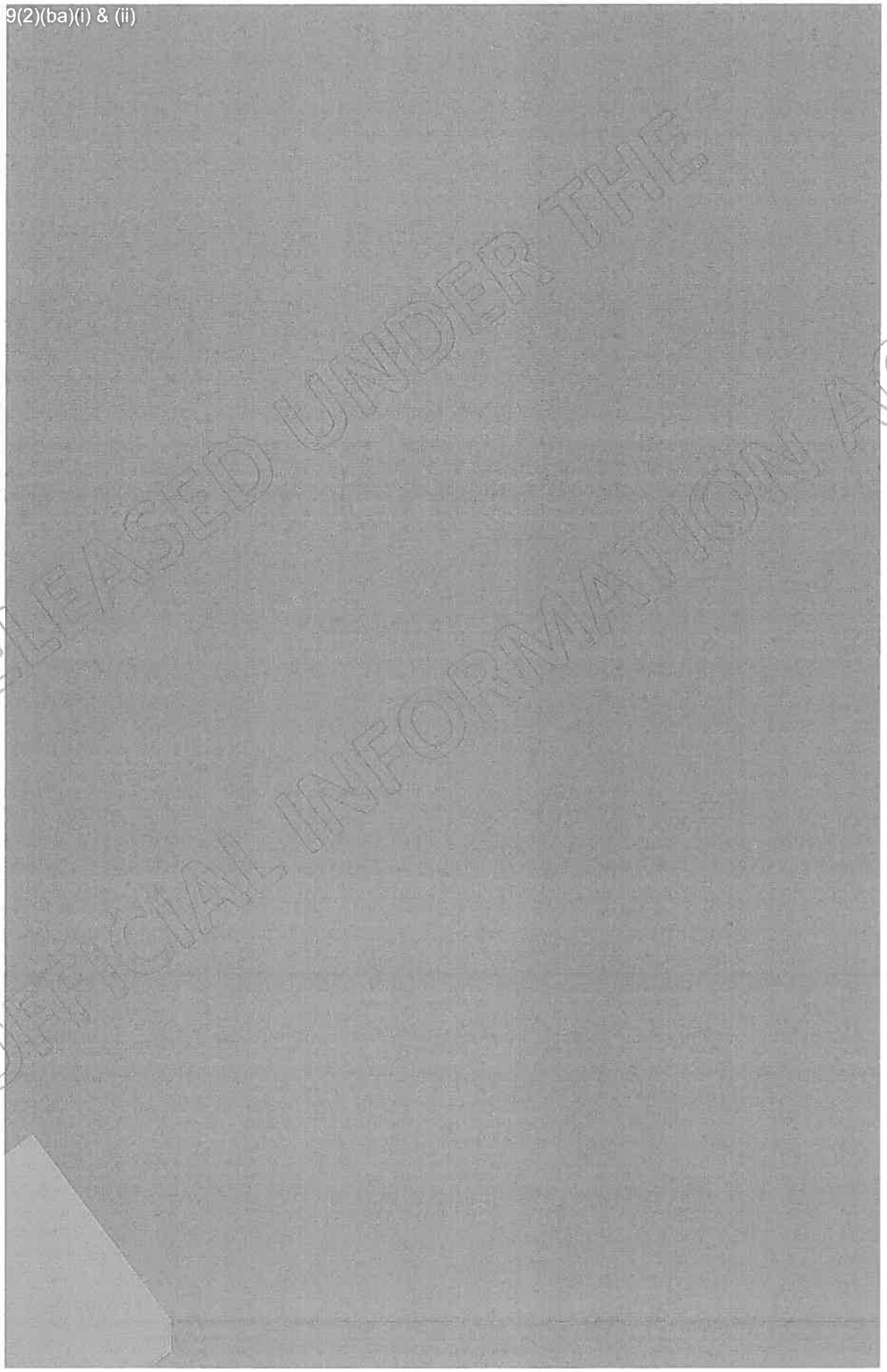
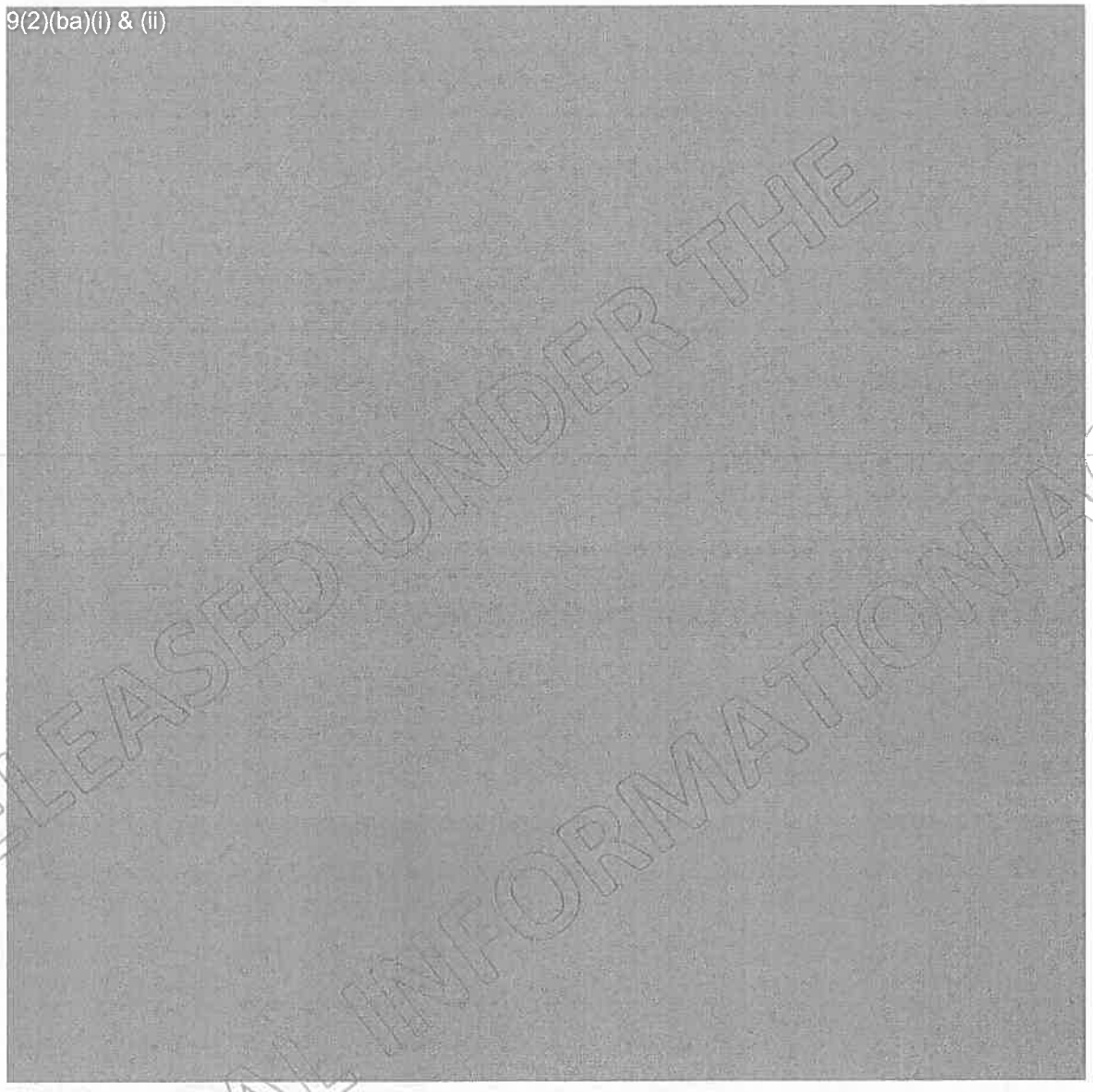
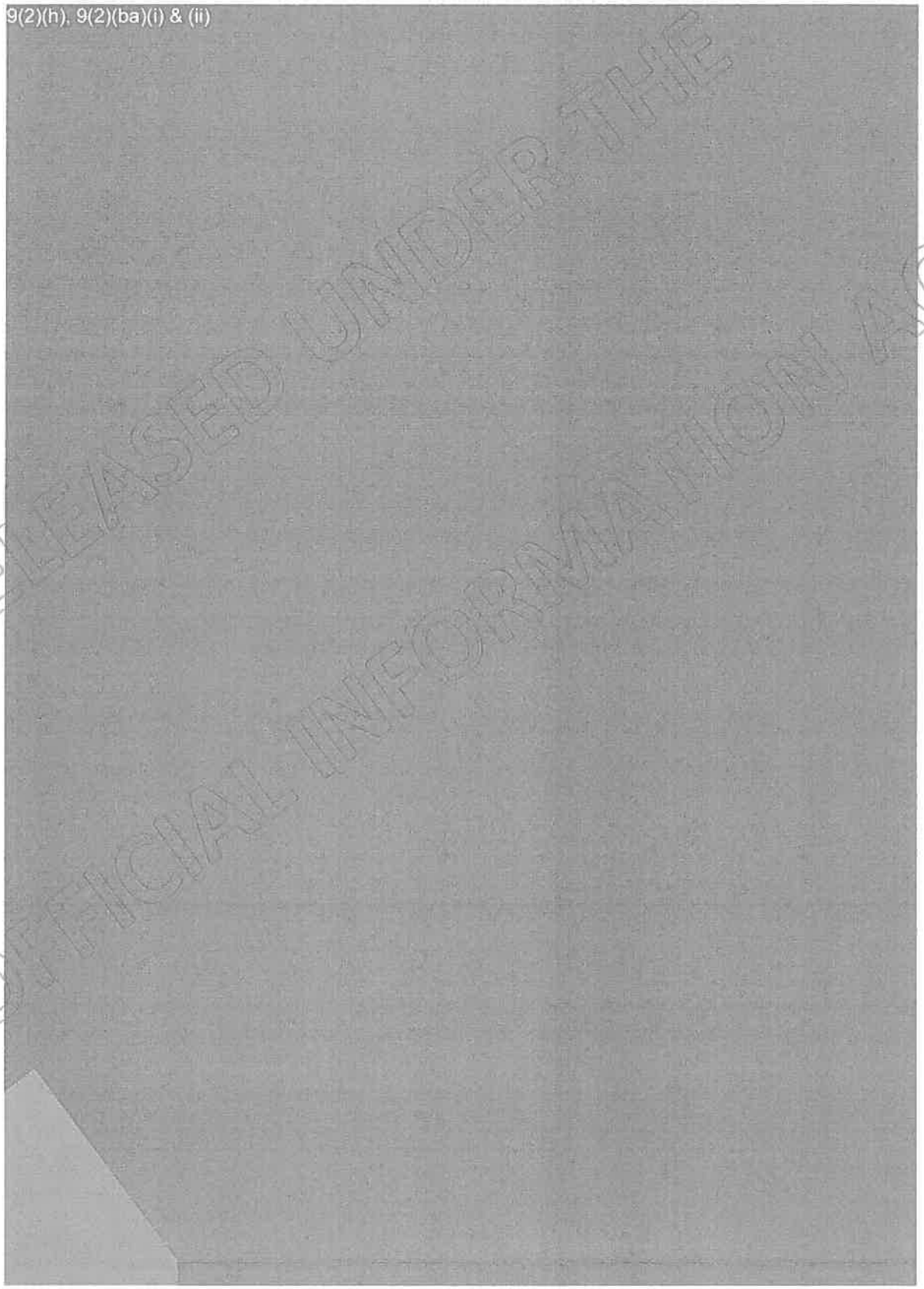


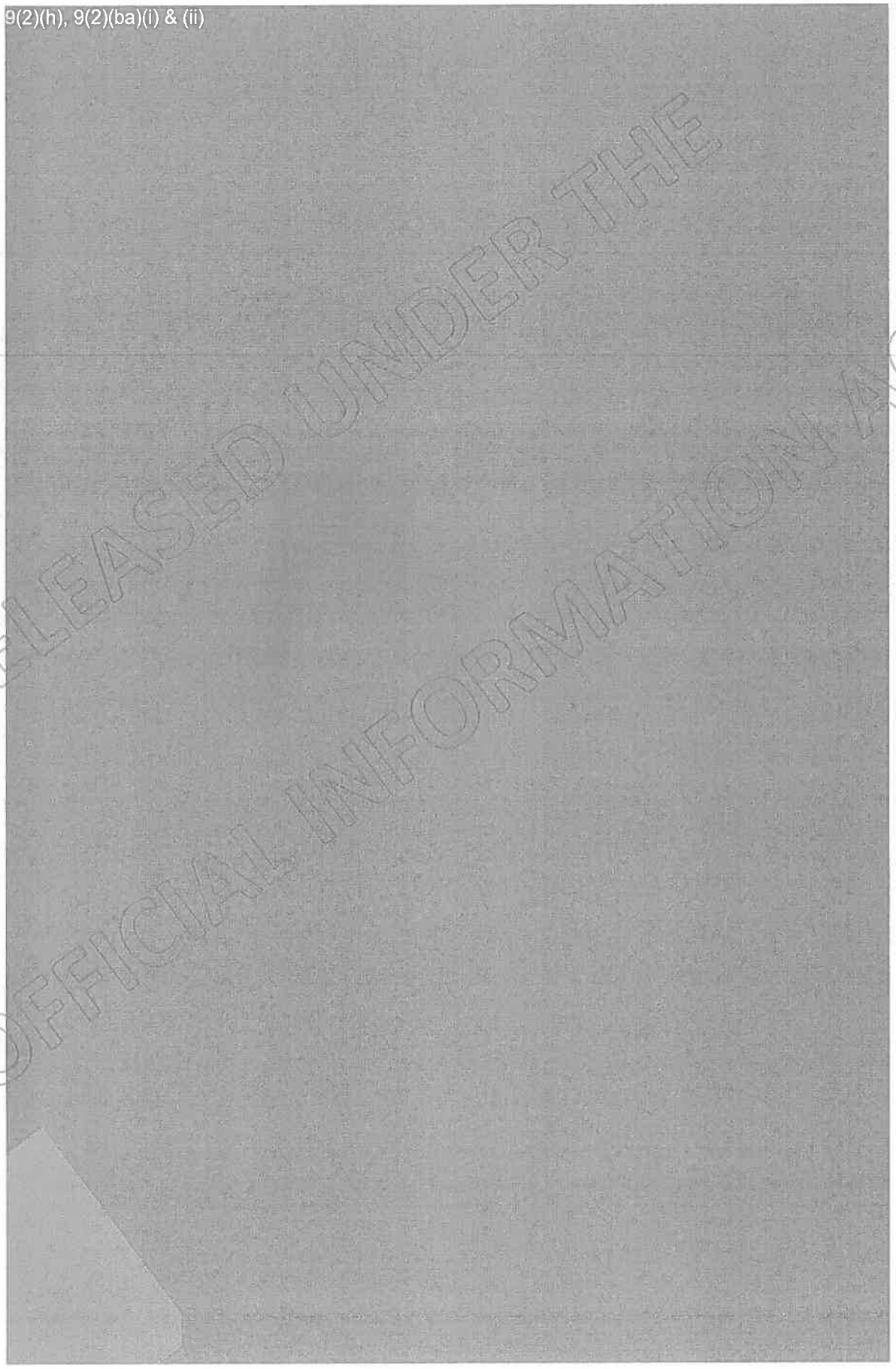
9(2)(ba)(i) & (ii)



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)

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.

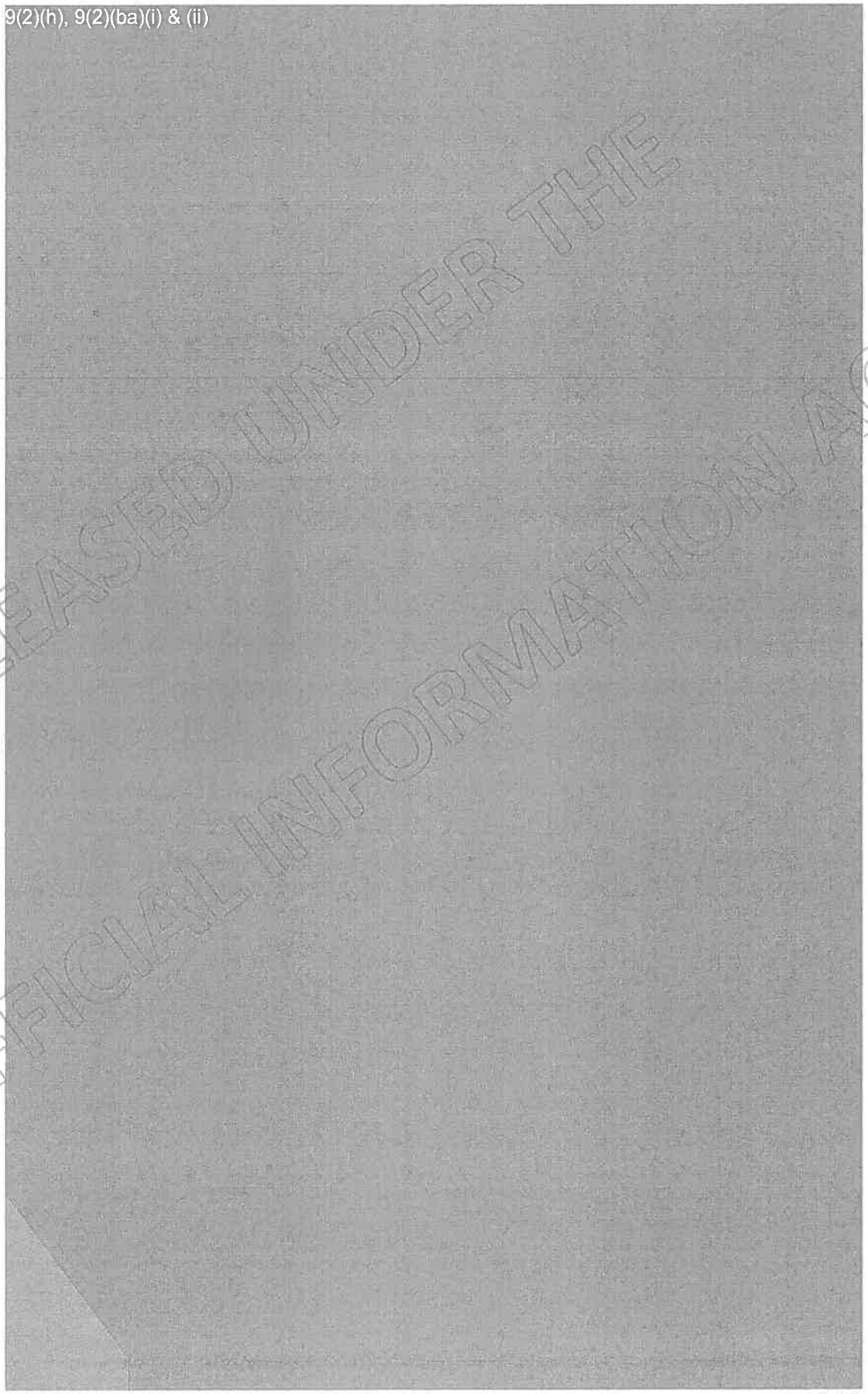
The liability associated with claims not covered by ACC is relatively low-risk

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.

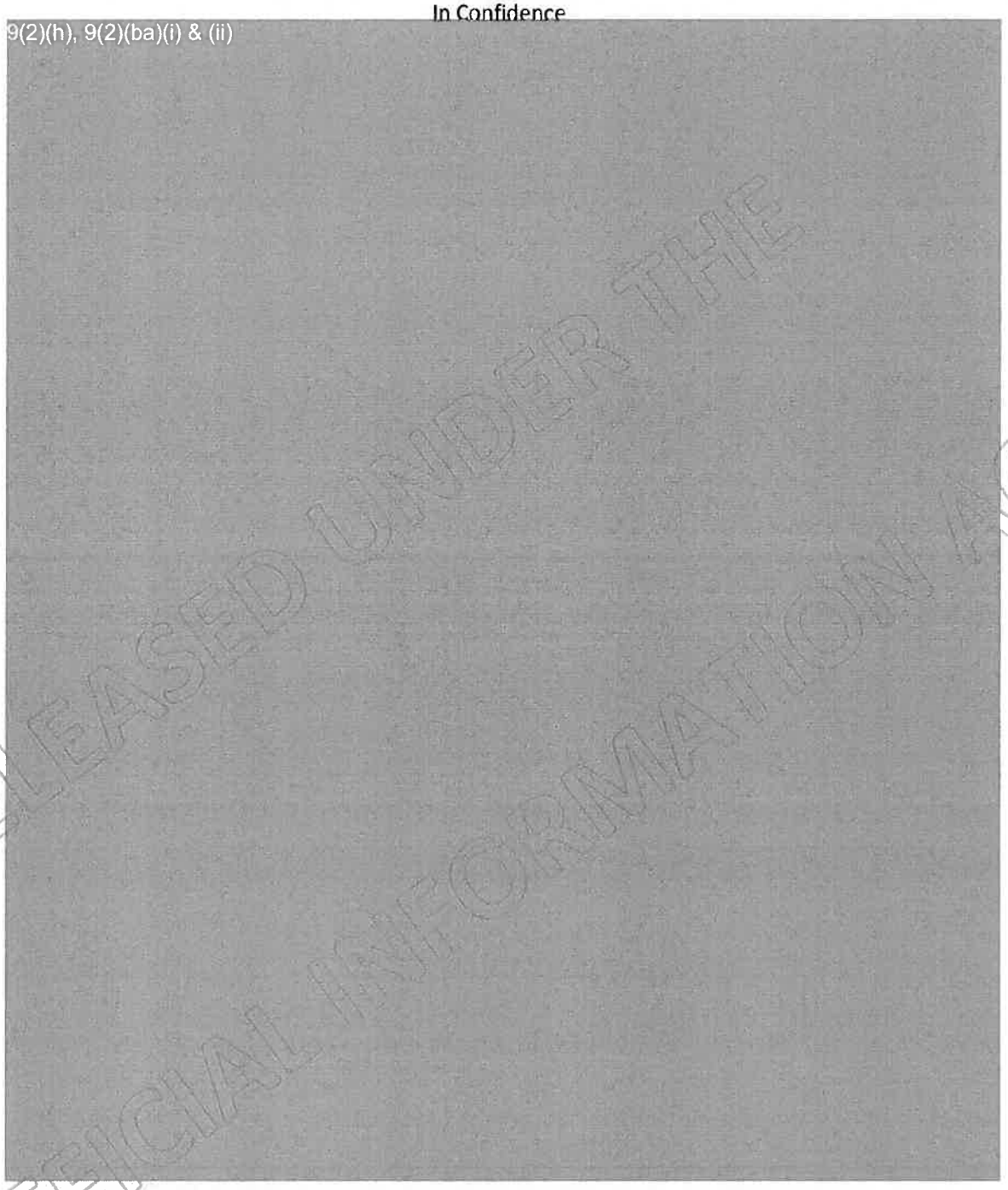
9(2)(h), 9(2)(ba)(i) & (ii)

[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.

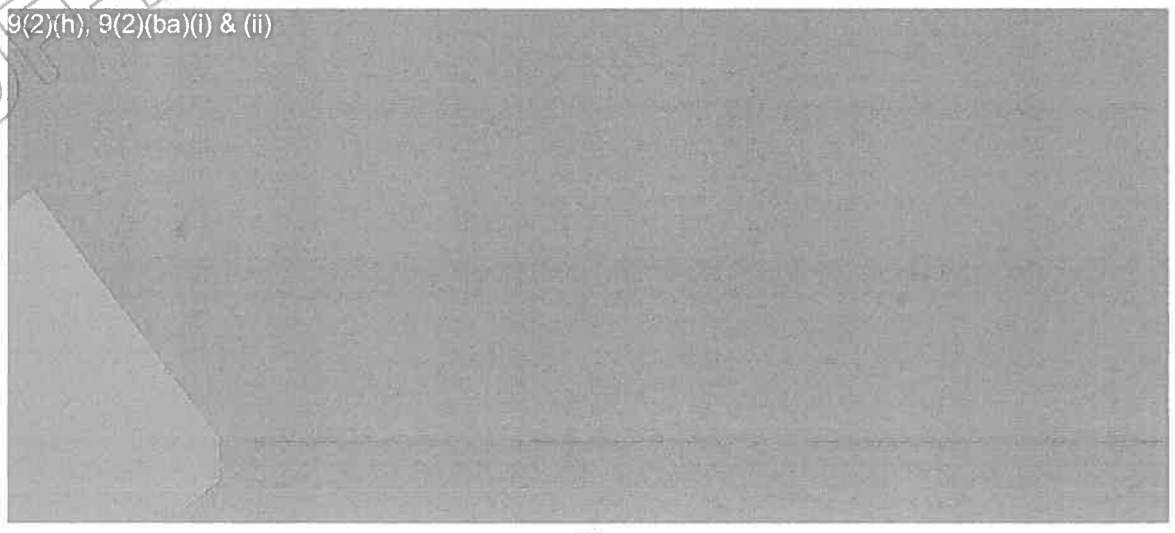
9(2)(h), 9(2)(ba)(i) & (ii)

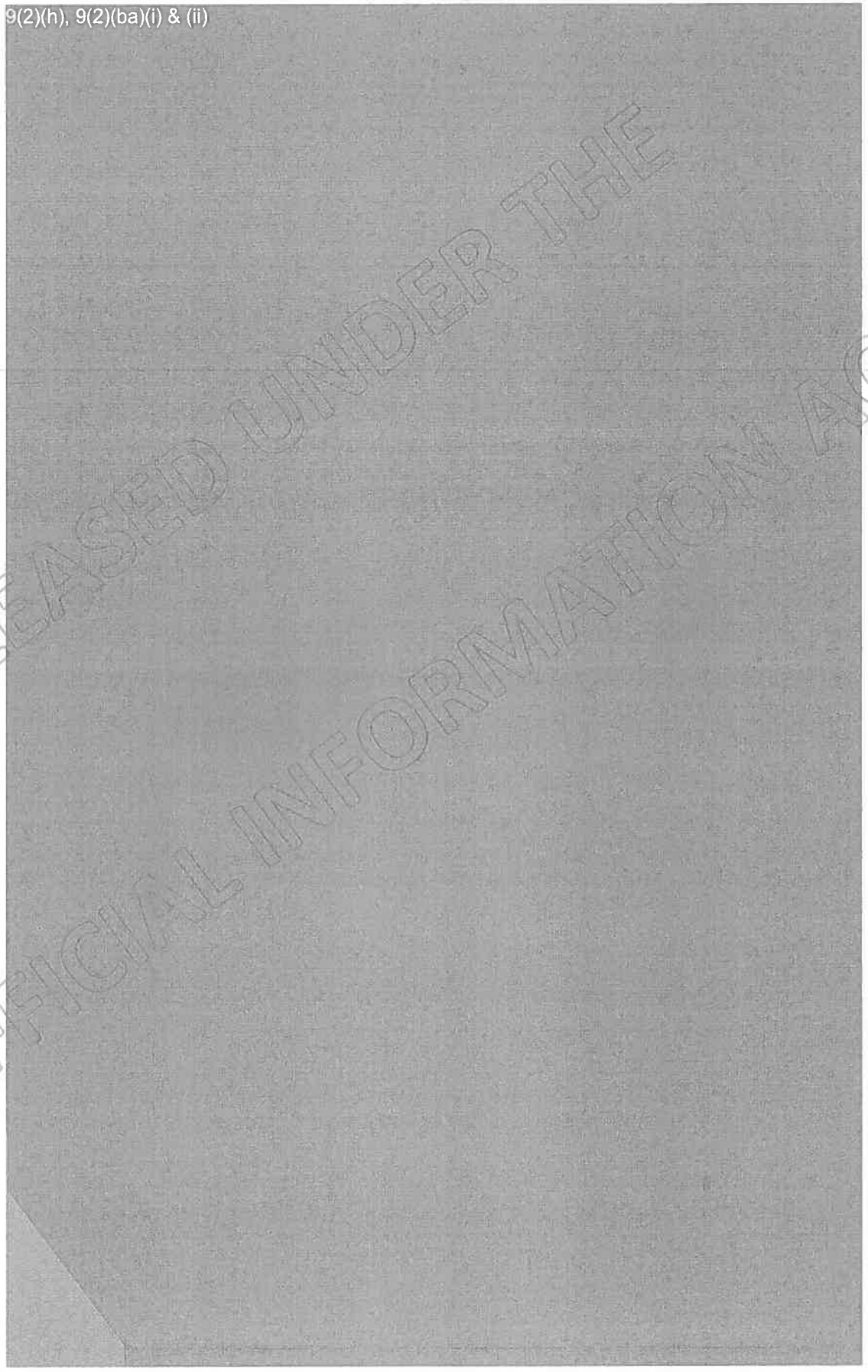


9(2)(h), 9(2)(ba)(i) & (ii)

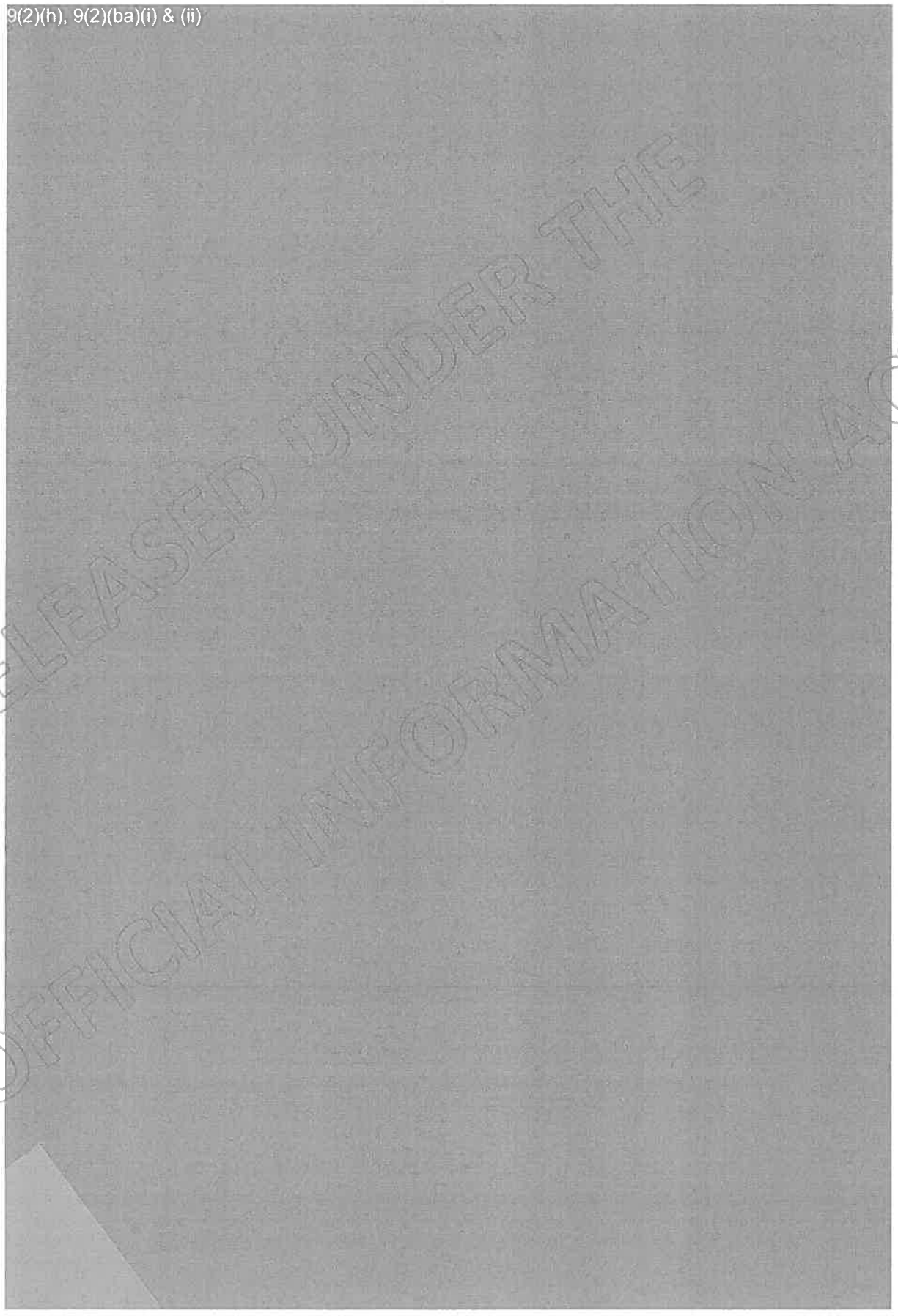


9(2)(h), 9(2)(ba)(i) & (ii)



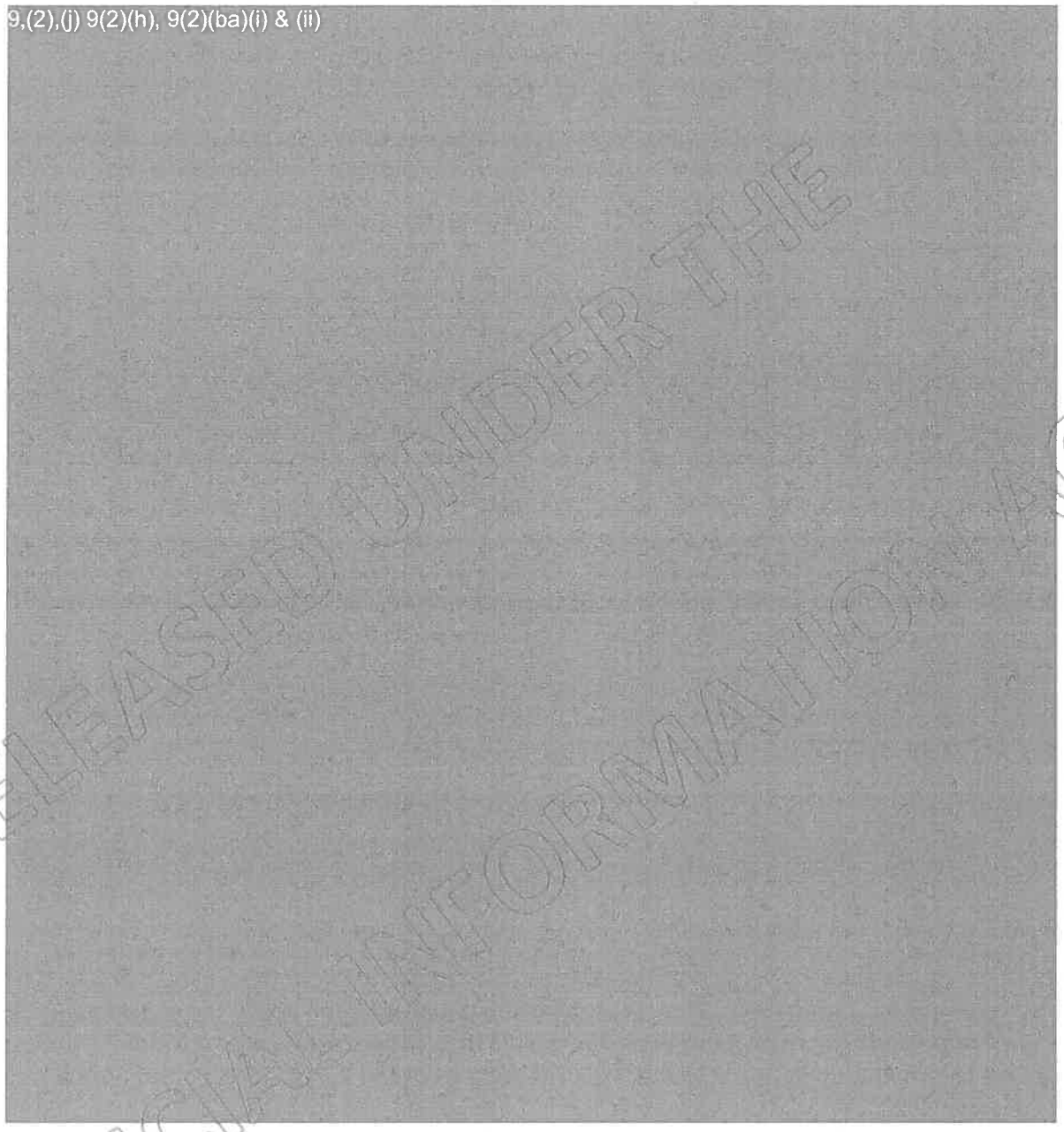


9(2)(h), 9(2)(ba)(i) & (ii)



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

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)
- 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)

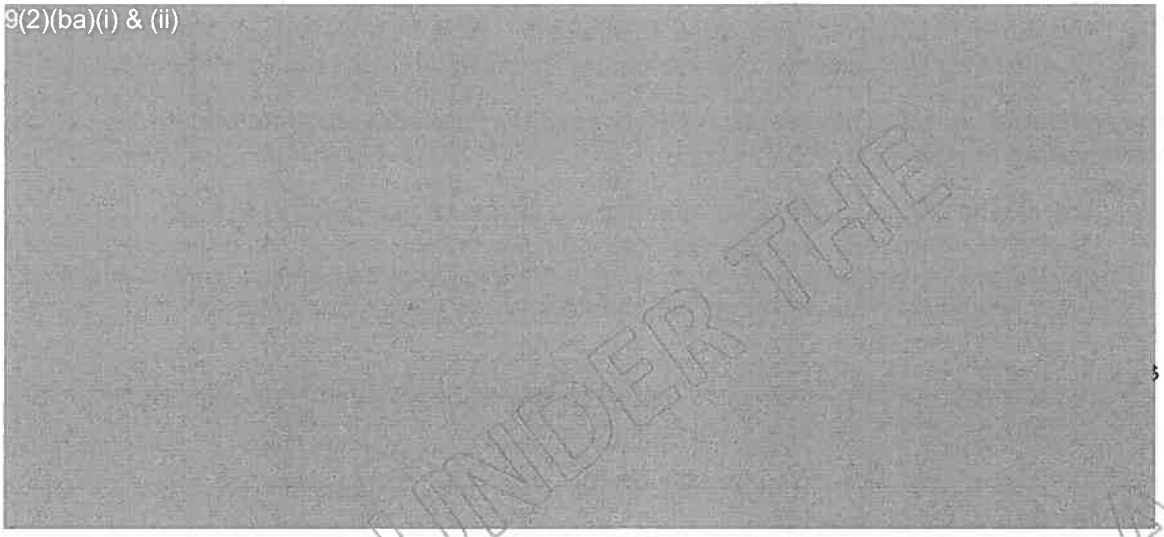
We are working to mitigate additional risks associated with the indemnity

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.

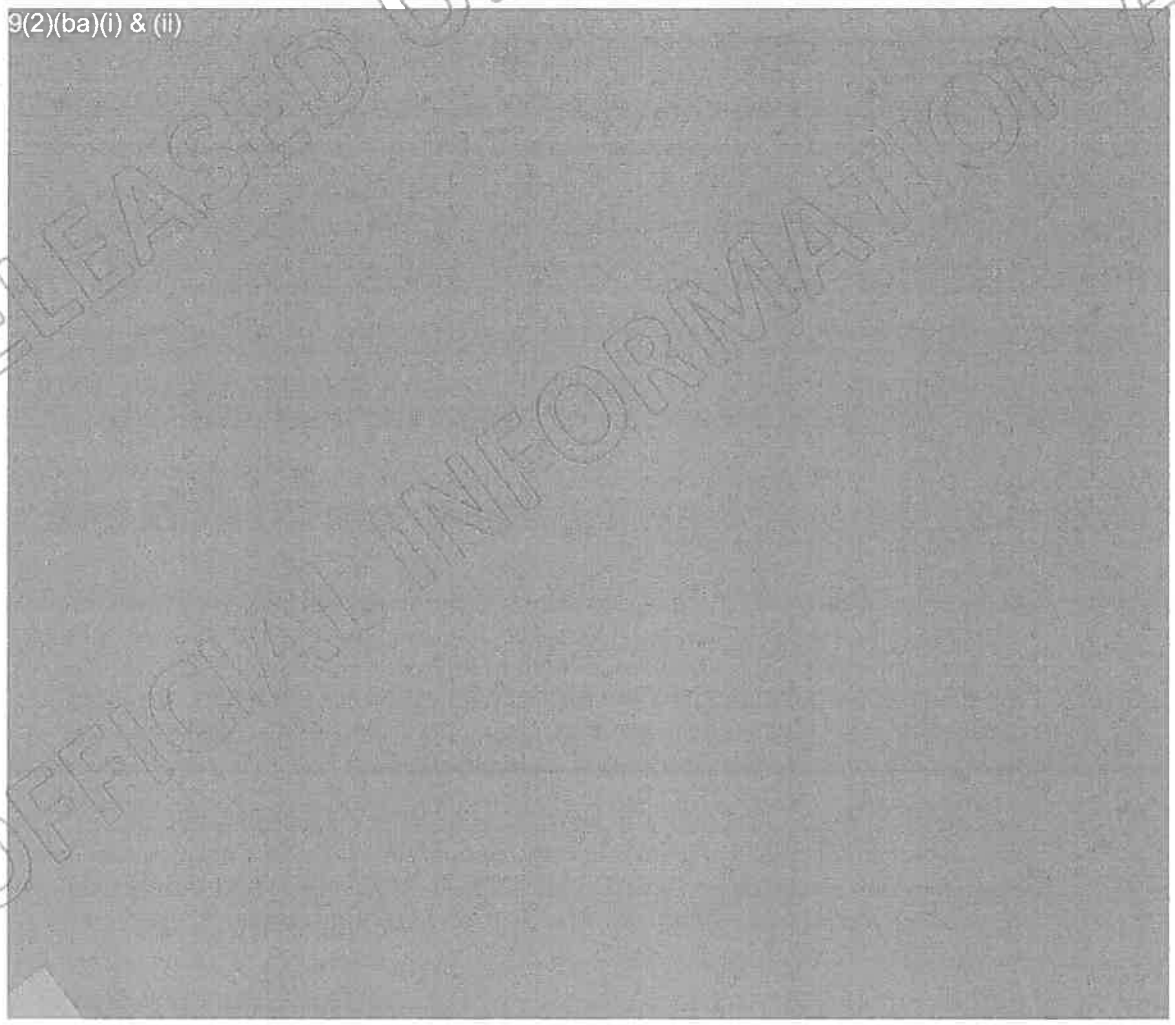
52. The indemnity could **reduce public confidence in the vaccine** and therefore reduce uptake. This might cause a flow-on in **reduced public confidence in vaccines in general**, potentially reducing immunisation rates for other diseases. This could ultimately result in reduced public confidence in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

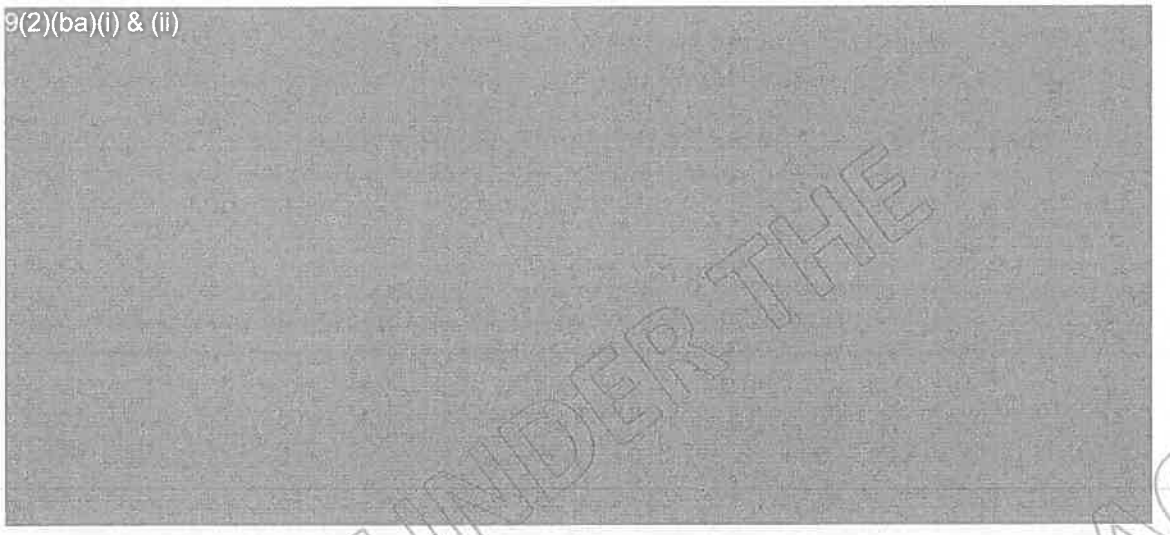
- Assuming that additional vaccines are purchased from Pfizer and an agreement is concluded with Novavax, we may need to consider purchasing a different vaccine candidate to form the core portfolio of four candidates with wide coverage. There is only one viable alternative at present, based on negotiations already underway. That vaccine candidate has not yet reported results from human trials, 9(2)(ba)(i) & (ii) [redacted] 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) [redacted] 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) [redacted]

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



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

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.

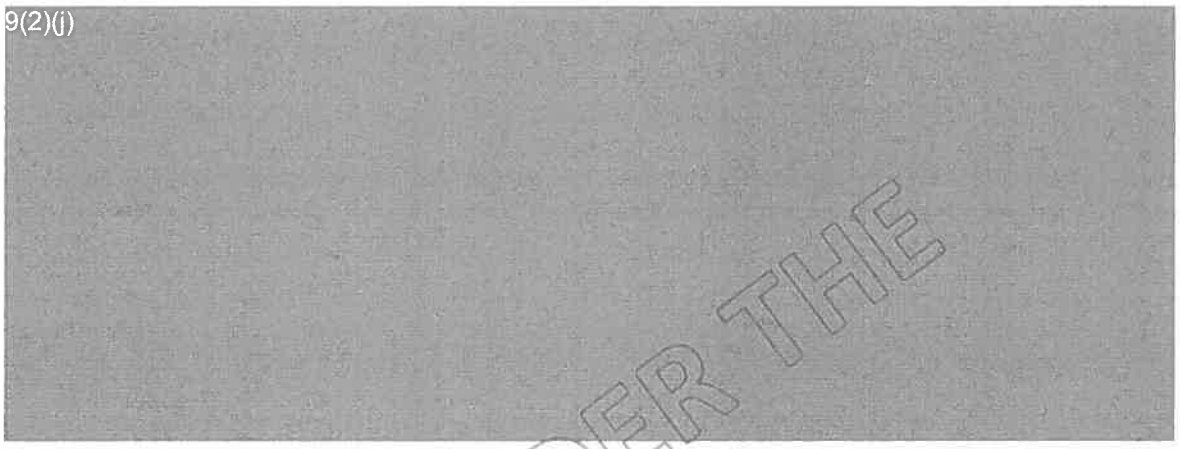
Our aim in negotiations on indemnity is to minimise the Crown's liability

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

[redacted]

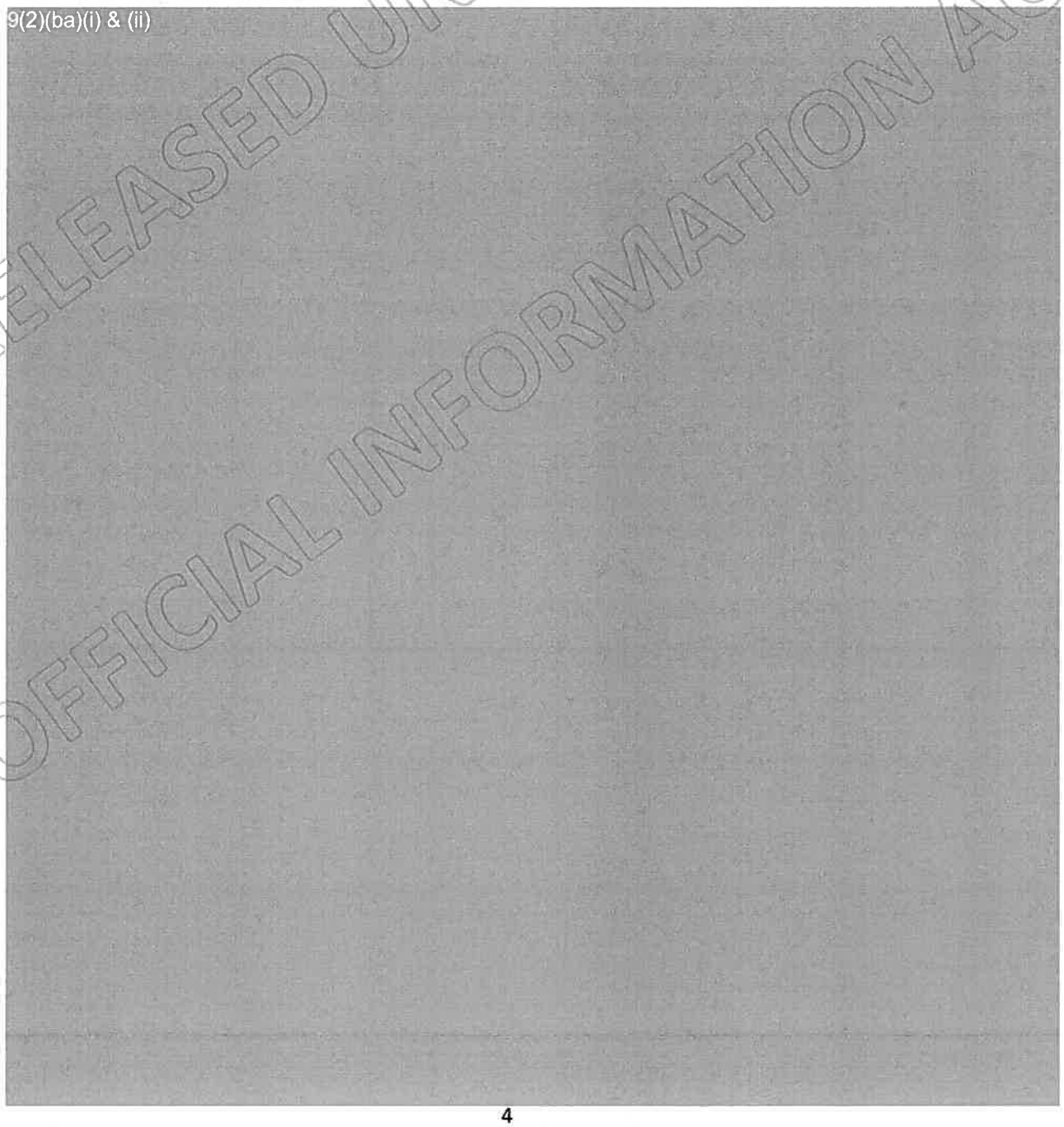
[5] Janssen will provide Medsafe with full clinical trials information when they apply for regulatory approval. Study designs and regulatory approaches will vary between COVID-19 vaccine applicants, but most trials will be shorter in length and study fewer people than what is typical. The impact is a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

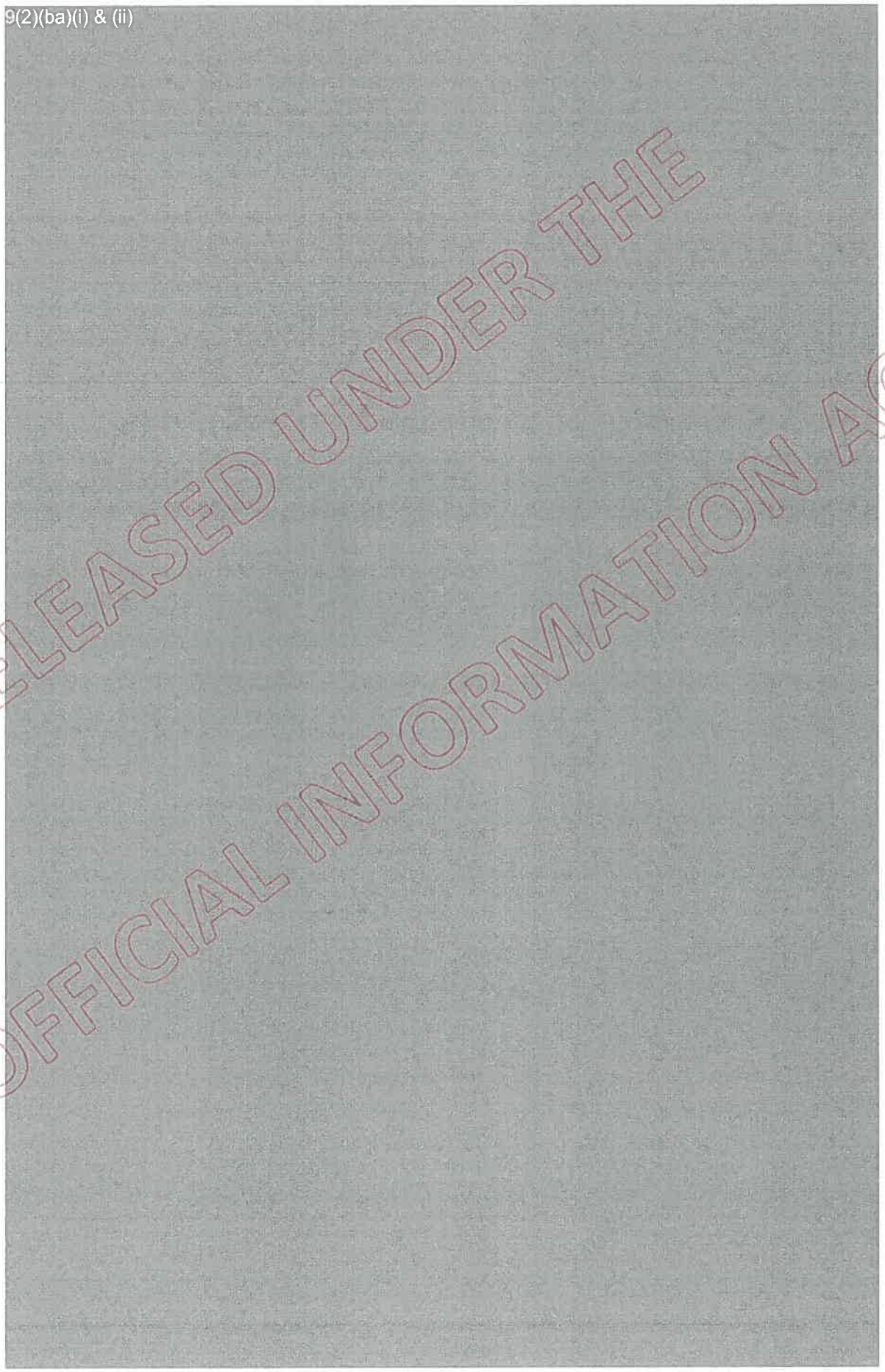


Scope of the indemnity

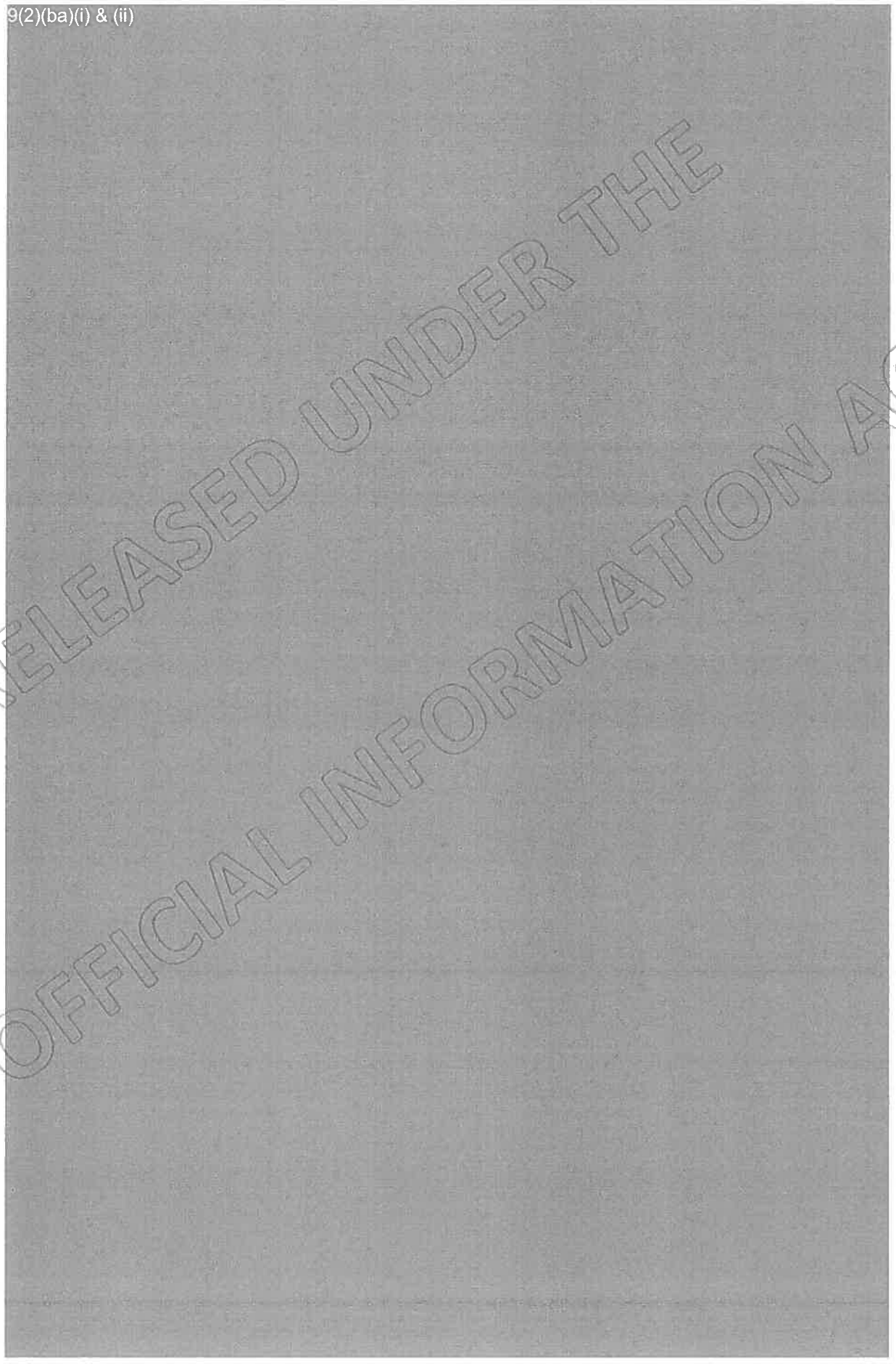
9(2)(ba)(i) & (ii)



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



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



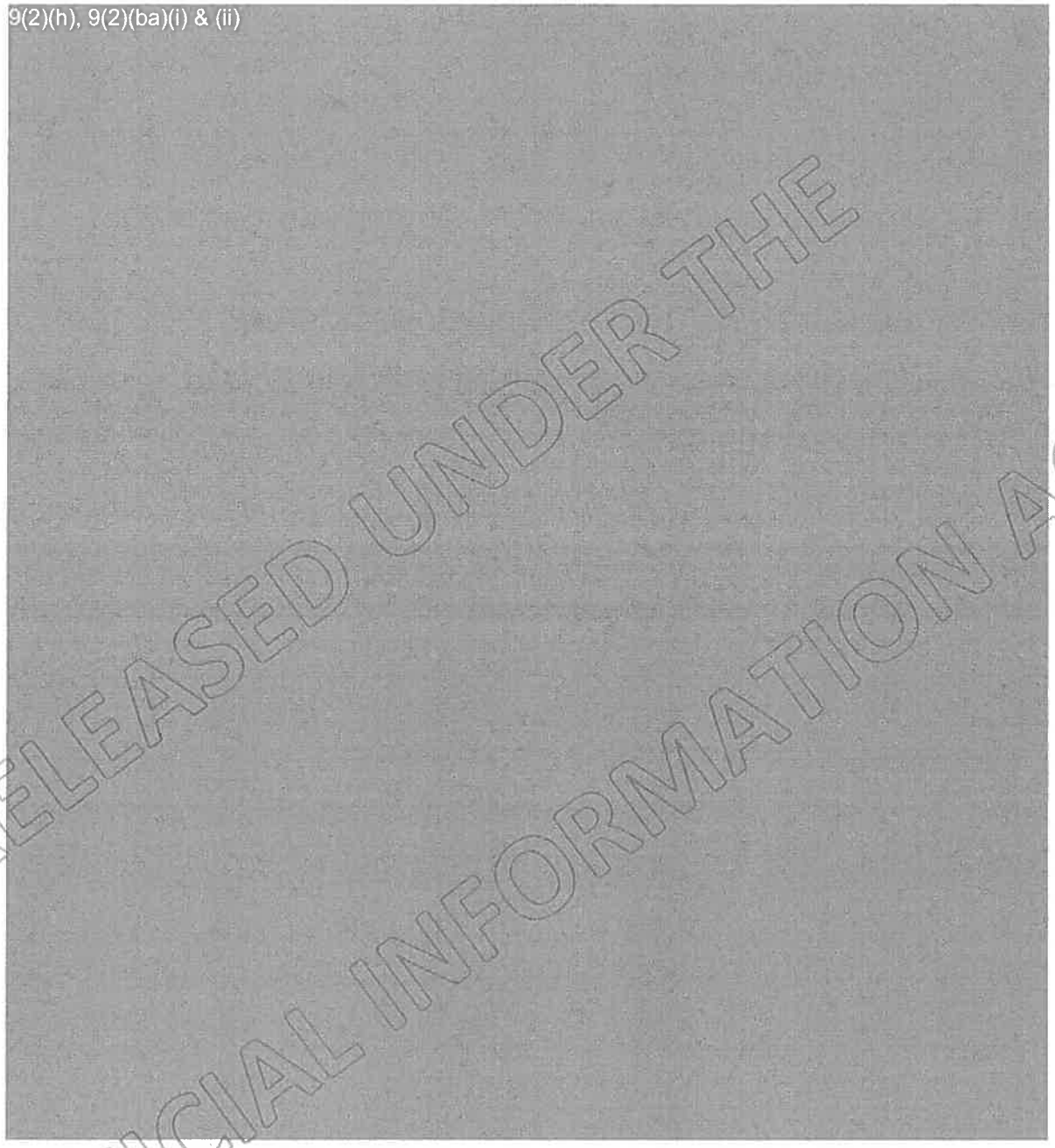
9(2)(ba)(i) & (ii)

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

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

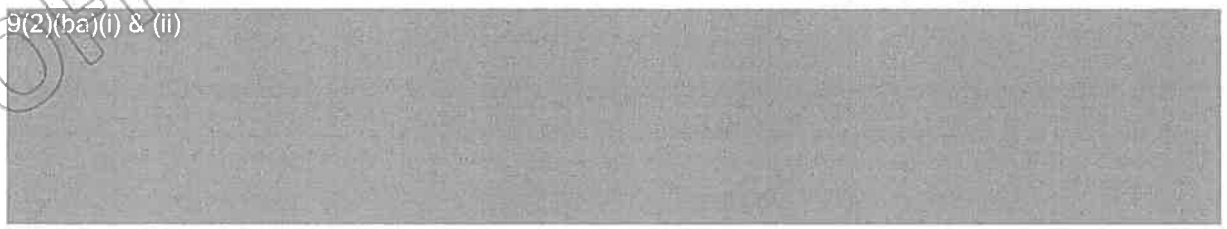
9(2)(h), 9(2)(ba)(i) & (ii)

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.

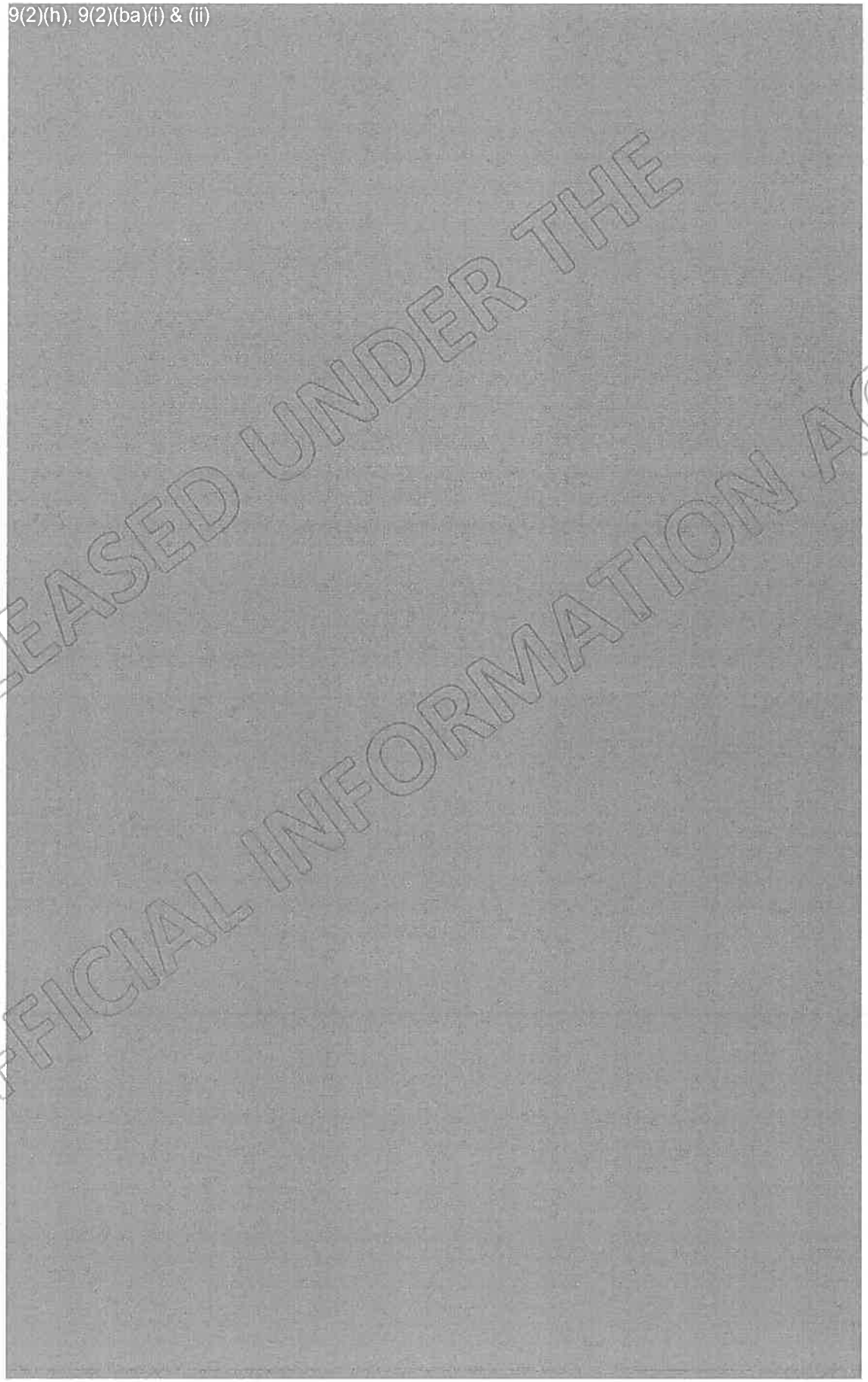
The liability associated with claims not covered by ACC is relatively low-risk

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)

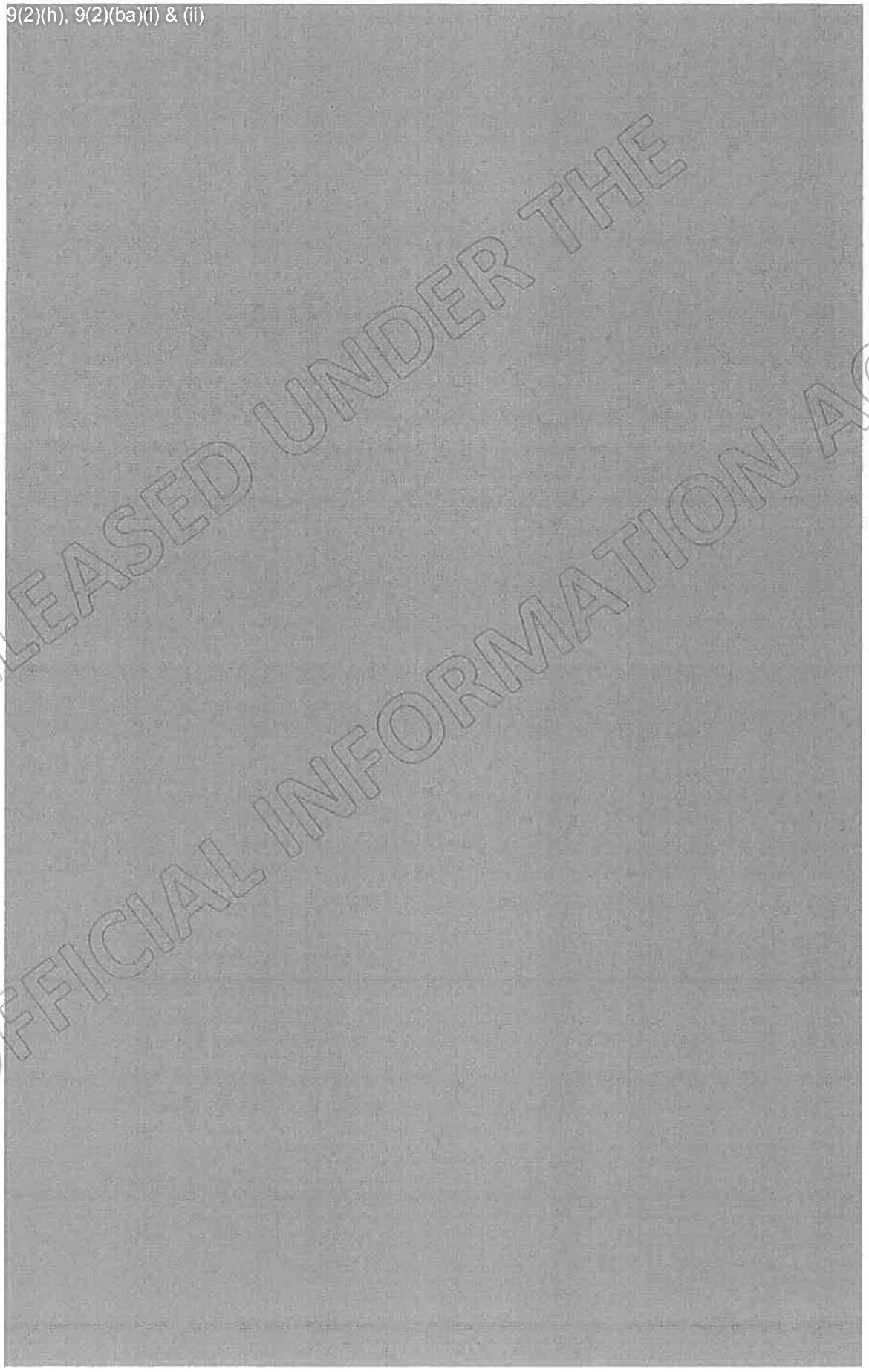
[6] Access to cover depends on the circumstances of the injury – including that there must be a clear causal link between the treatment and the injury, and the injury must not be a necessary part or ordinary consequence of the treatment.

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

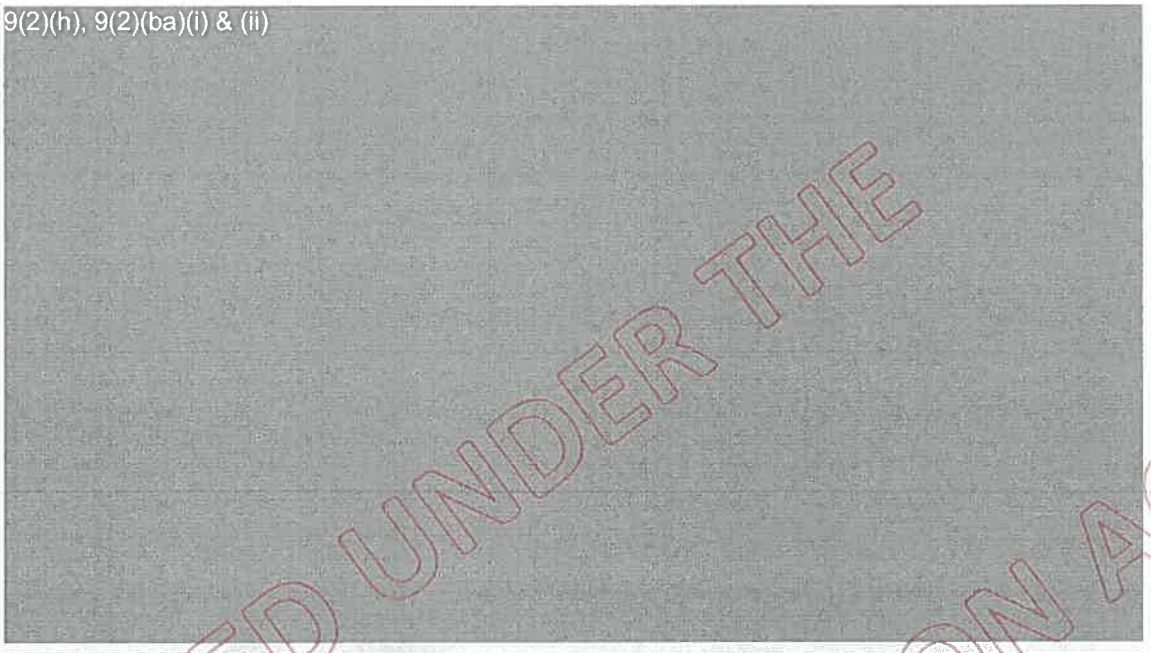


9(2)(h), 9(2)(ba)(i) & (ii)

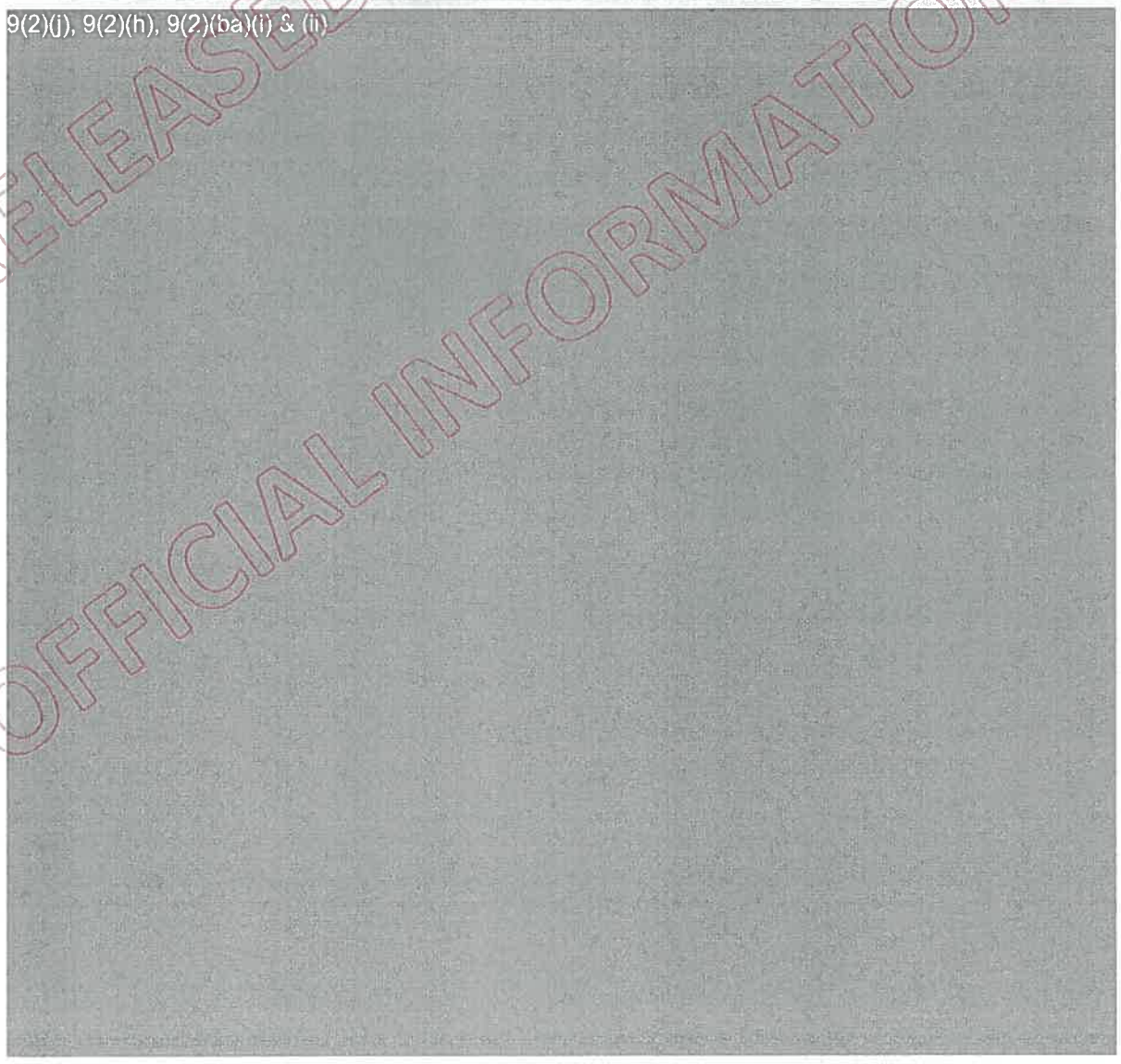
9(2)(h), 9(2)(ba)(i) & (ii)



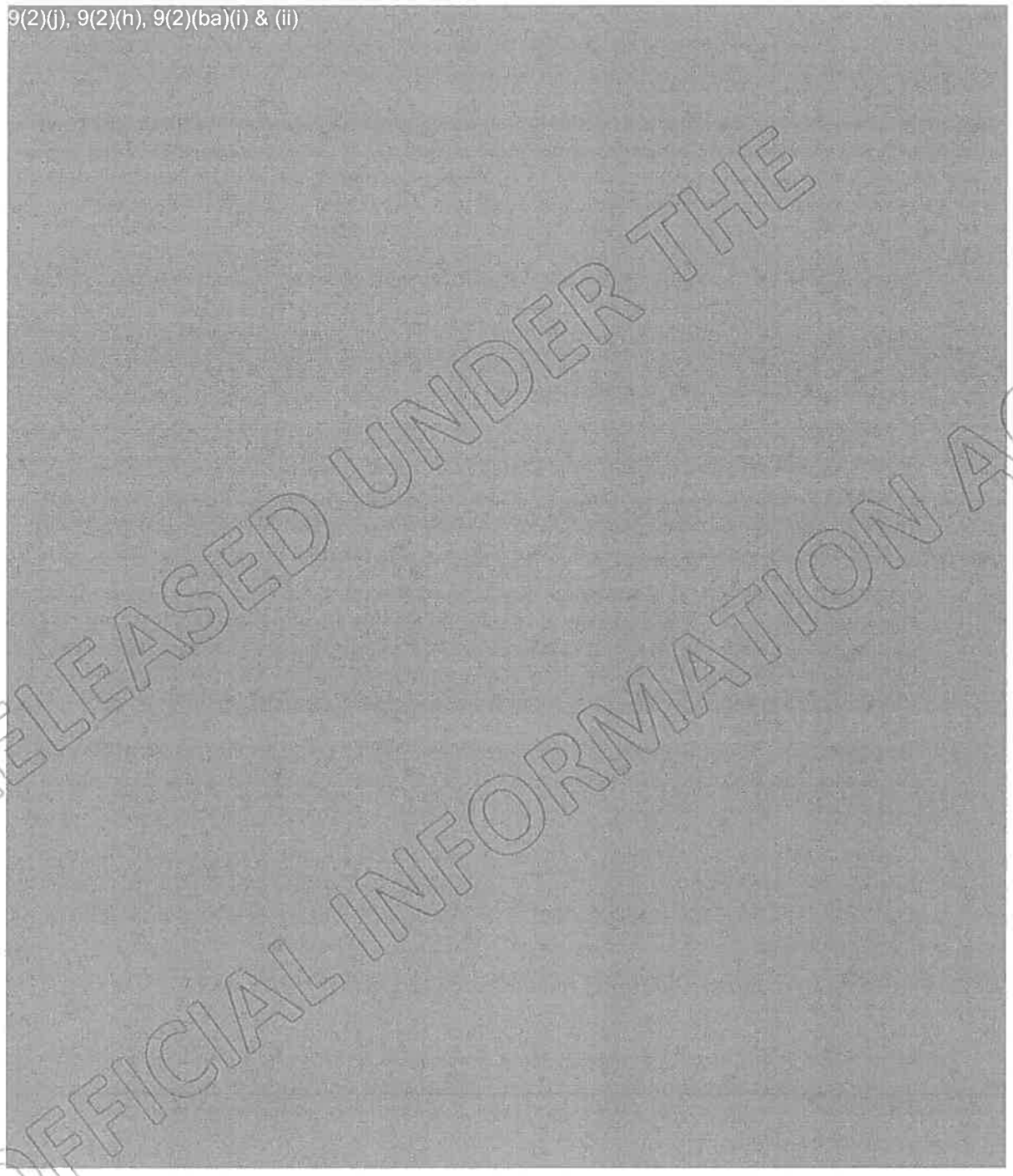
9(2)(h), 9(2)(ba)(i) & (ii)



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



9(2)(j), 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)			

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)
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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

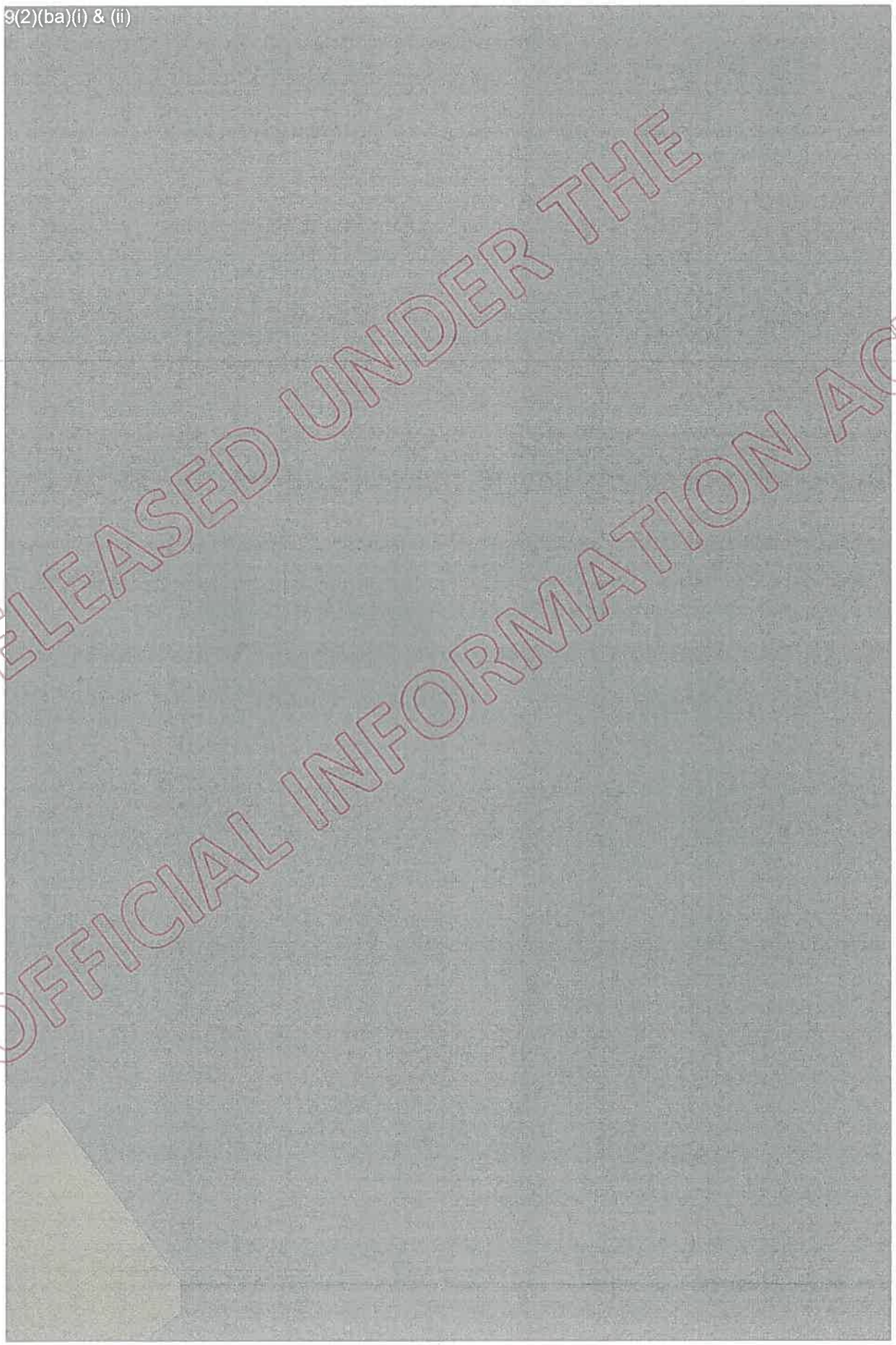
13. In order to minimise the Crown's liability, in negotiations with pharmaceutical companies we are seeking 9(2)(i)

9(2)(i)

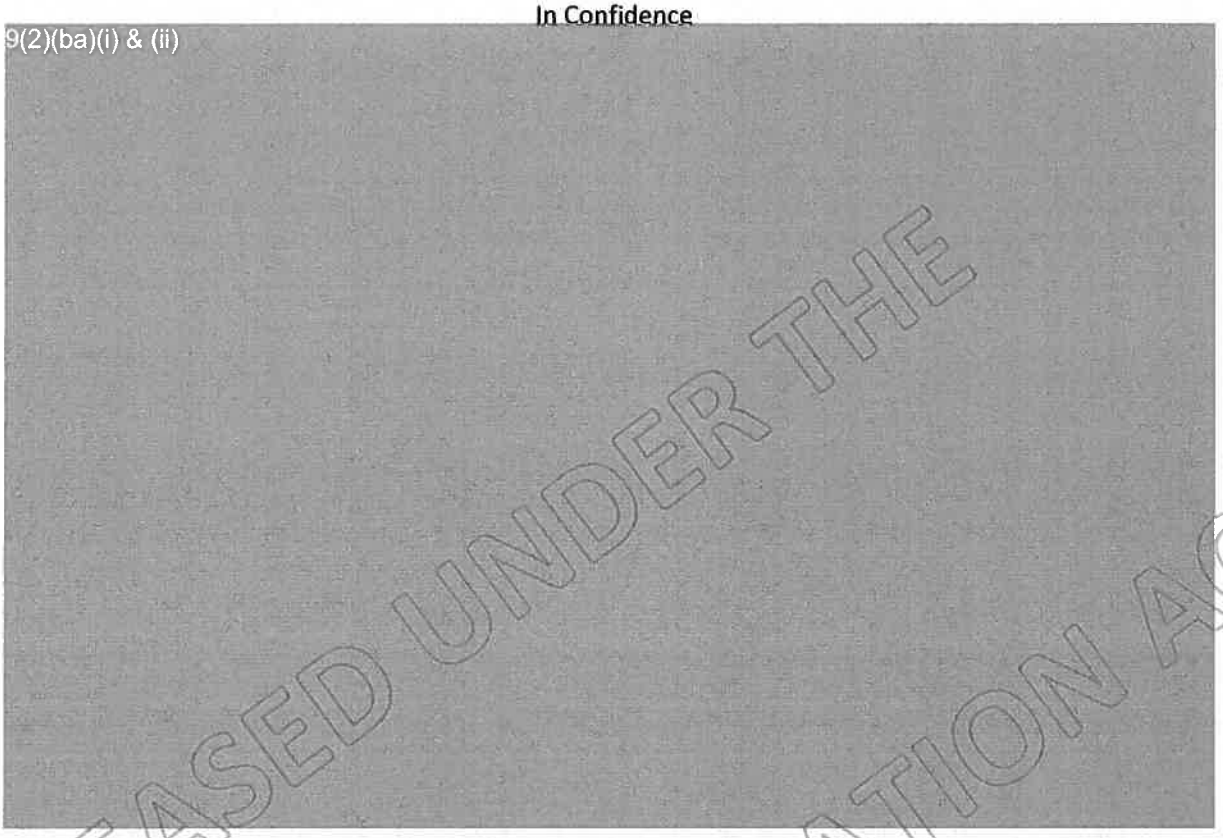
Scope of the indemnity

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)



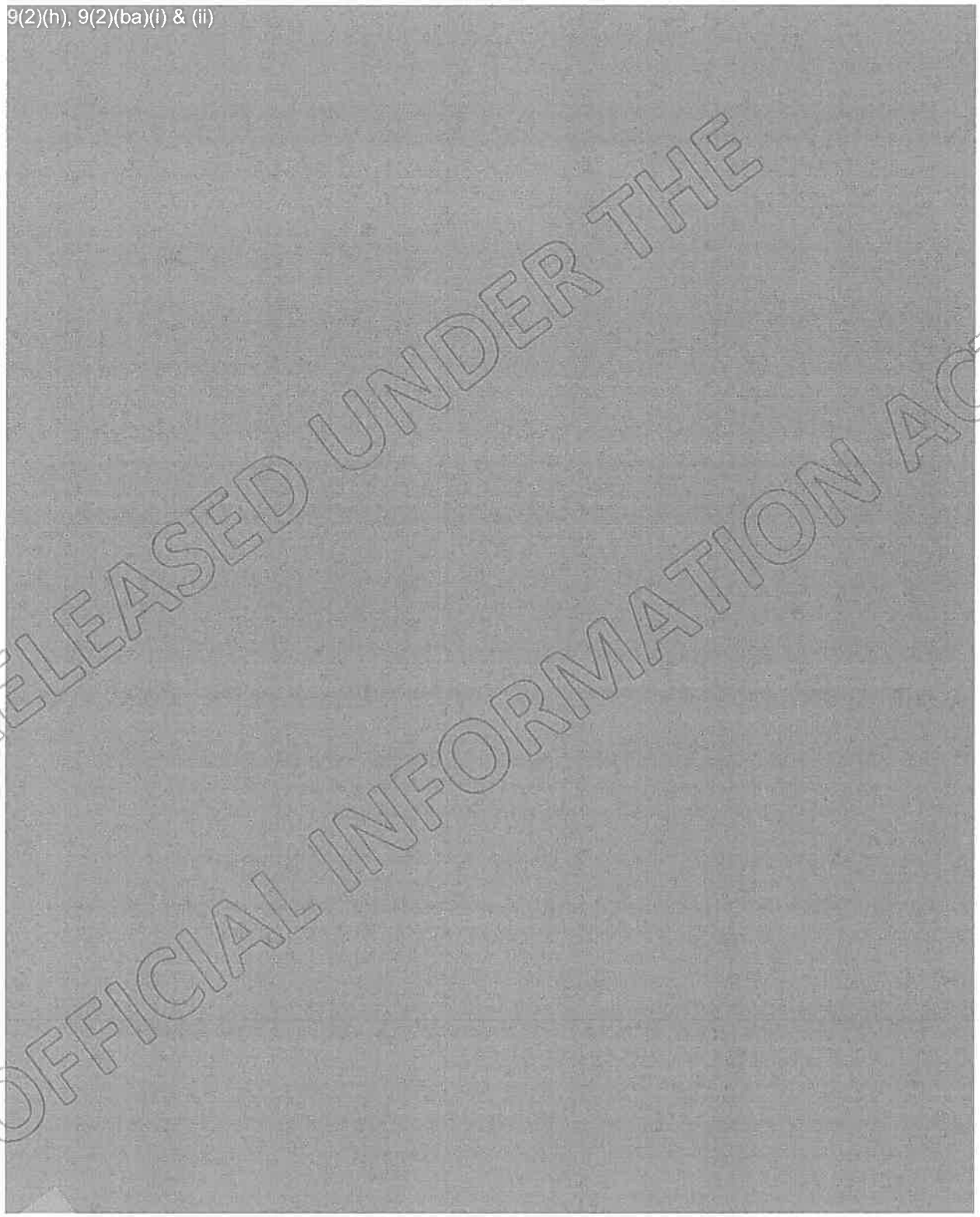
17. Bell Gully has provided the following explanation of the provisions:

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) [redacted]

Exposure, risk and mitigation

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

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

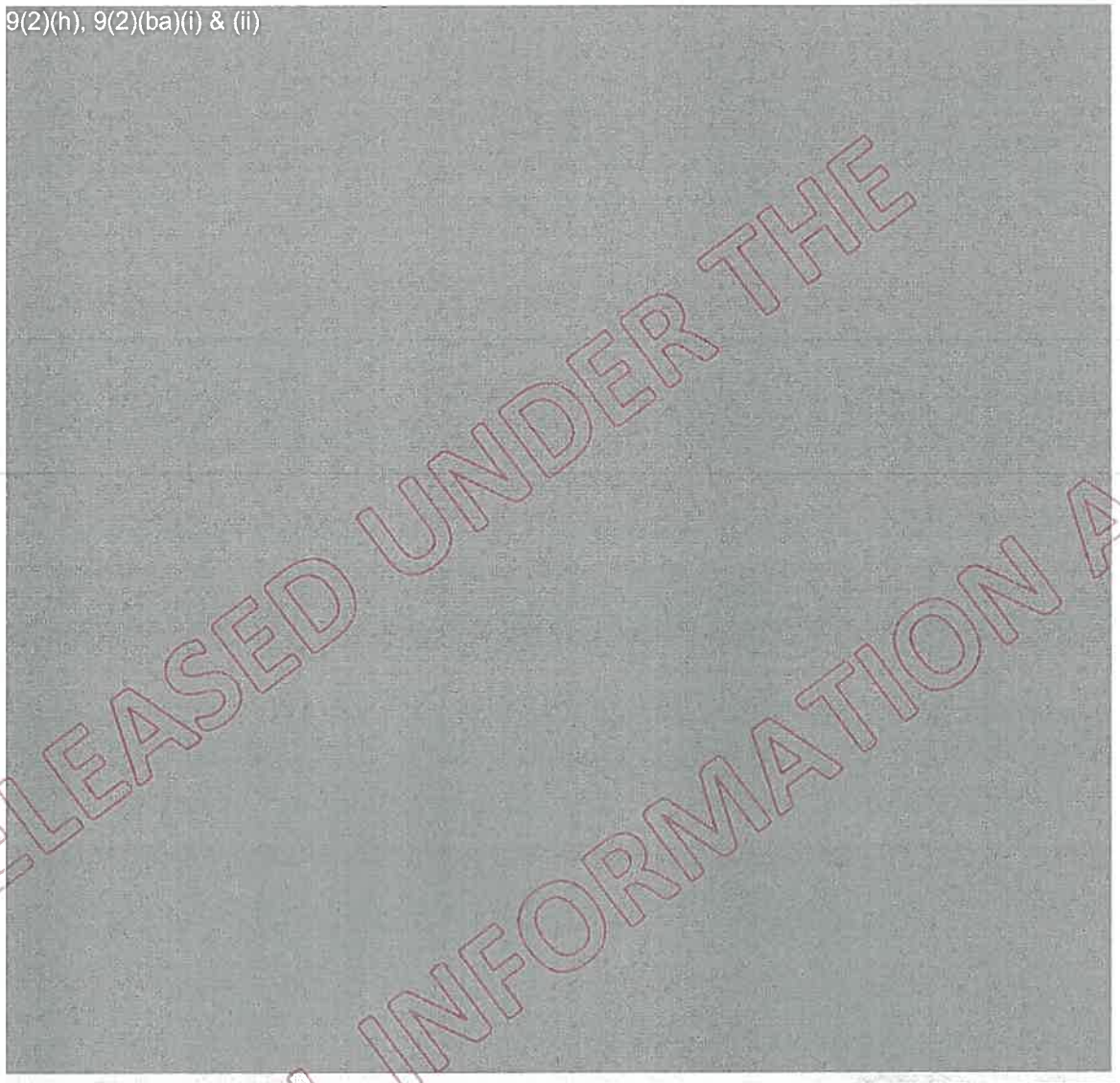
29. Bell Gully has advised that "overall, the risks associated with claims 9(2)(h), 9(2)(ba)(i) & (ii) [redacted] which would not be covered by the AC Act seem likely to be relatively low (particularly when assessed against the risks of not accessing a vaccine), with the Crown able to take certain steps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

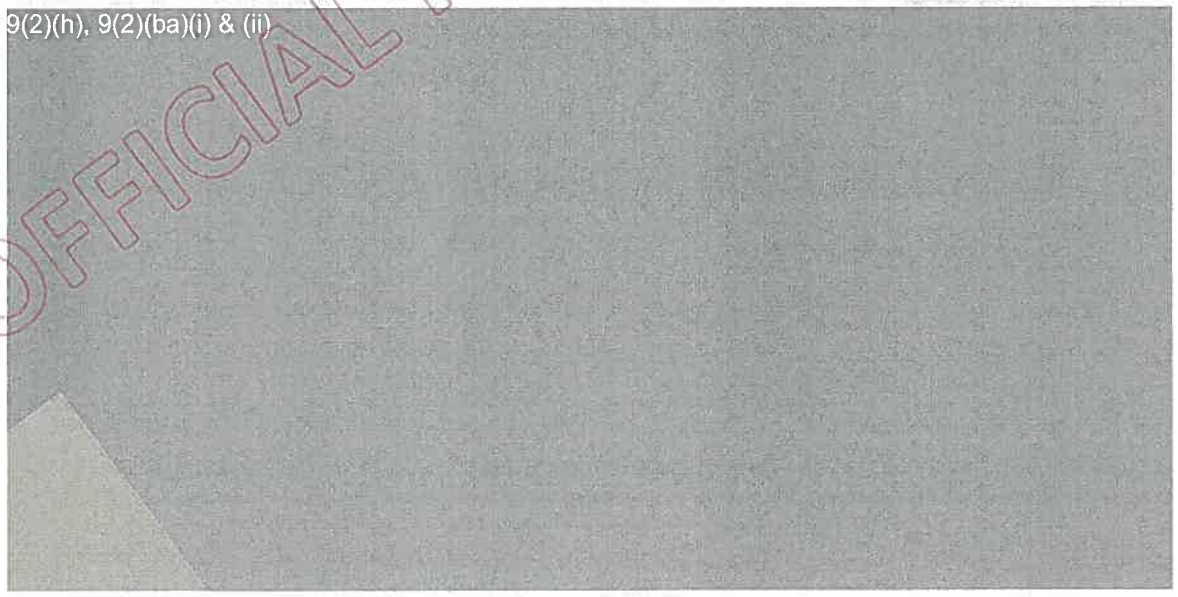
[6] Access to cover depends on the circumstances of the injury – including that there must be a clear causal link between the treatment and the injury, and the injury must not be a necessary part or ordinary consequence of the treatment.

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

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



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



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

[redacted]

9(2)(i)

[redacted]

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

[redacted]

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

[redacted]

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) [redacted] – 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) [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

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

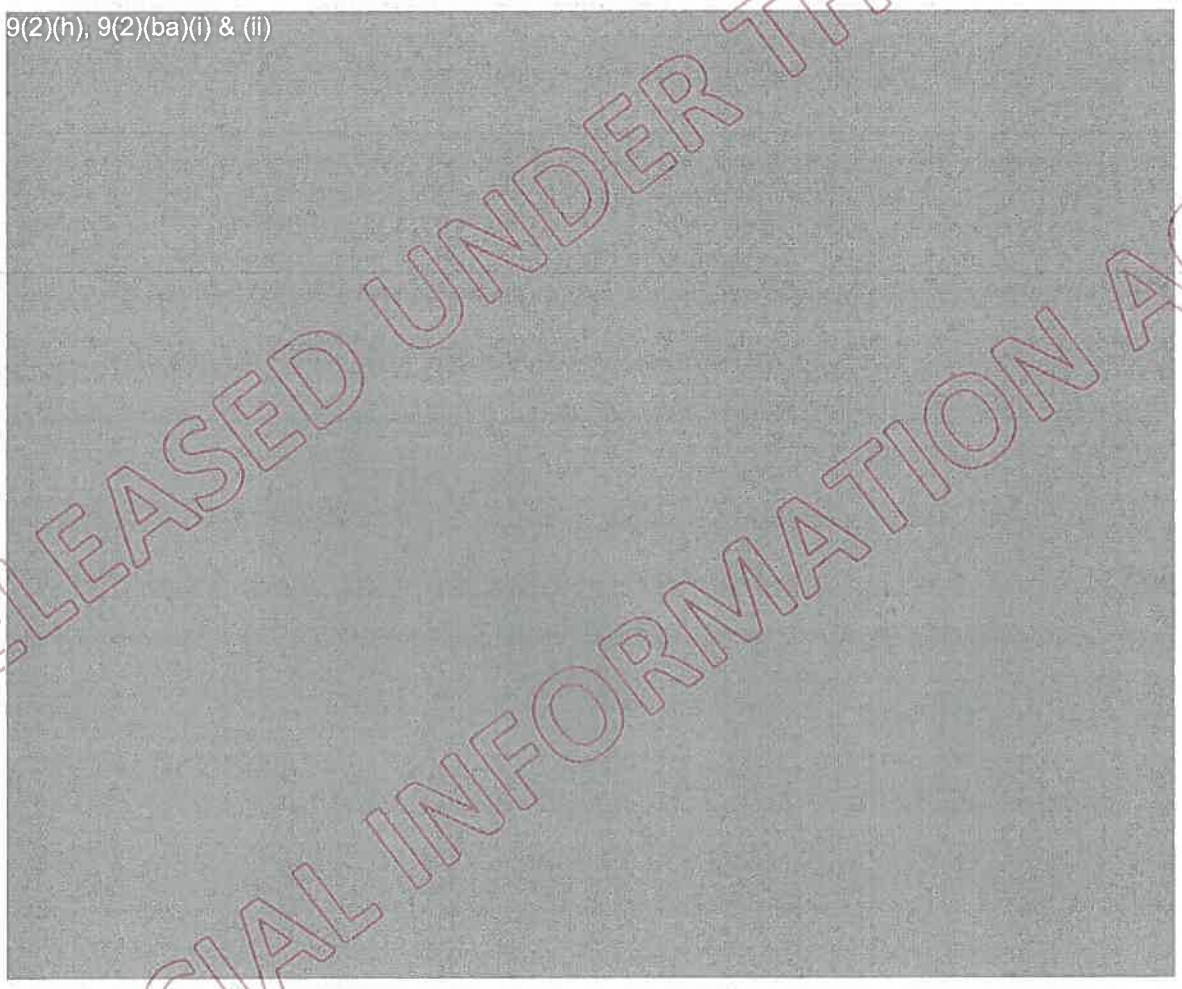
[7] 9(2)(ba)(i) & (ii)

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%
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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)			

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

Introduction

1. Negotiations have concluded on binding terms for purchase of vaccines from Pfizer and BioNTech.

2. Pfizer Inc has offered New Zealand 750,000 courses (1.5 million doses) of a vaccine candidate (known as BNT162) developed with BioNTech, an mRNA vaccine against COVID-19 infection. Subject to successful trials and regulatory approval, the supplier expects to deliver the courses over the first three quarters of 2021. The vaccine will cost 9(2)(ba)(i) and (ii), including an advance payment of 9(2)(ba)(i) and (ii) at a total cost of 9(2)(ba)(i) and (ii) million 9(2)(ba)(i) and (ii)
The vaccine consists of two doses, each delivered intramuscularly 28 days apart.

3. 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. 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.

4. The offer from Pfizer/BioNTech is made in the form of a binding term sheet, and is attached as Annex One. 9(2)(ba)(i) and (ii) The Definitive Agreement is likely to contain other terms typically found in pharmaceutical supply and funding agreements, which may include terms in past agreements between Pfizer and PHARMAC to the extent they do not conflict. 9(2)(ba)(i) and (ii)

5. As part of the binding term sheet Pfizer and BioNTech are seeking an indemnity for liability associated with the possession, distribution and/or use and administration of BNT162 in New Zealand. This is because:

   a. they are developing it in accelerated clinical trials that are less likely than non-accelerated trials to detect uncommon adverse effects or possible contraindications.[1]
   b. 9(2)(ba)(i) and (ii)

6. Pfizer/BioNTech have indicated that they do not plan to include any further indemnity provisions in the Definitive Agreement.

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

[1] Pfizer/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)

Background

8. 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. For example, indemnity clauses are common in Advanced Purchase Agreements (APAs) between pharmaceutical companies and governments internationally for the supply of pandemic influenza vaccines.

Previous indemnities

9. The Minister of Finance has given an indemnity in relation to influenza vaccine on four occasions:

- A **2016 APA with Seqirus Ltd** (previously bioCSL and CSL), renewing a **2005 APA with CSL** for the supply of H5N1 pre-pandemic vaccine
- A **2009 APA with Baxter Healthcare Ltd** for supply of pandemic flu vaccine
- A **2007 contract with Baxter Healthcare Ltd** for the supply of 100,000 vaccination courses of H5N1 non-pandemic vaccine.

10. 9(2)(j) [redacted]

11. The circumstances of the previous cases differ from the present situation in two main respects:

(a) In the previous cases the pharmaceutical companies sought indemnity because the contract was for the supply of vaccine against a **potential future pandemic virus. Clinical trials were not possible** either because the vaccine did not yet exist, or its efficacy on a different strain of influenza was unknown.

In contrast, BNT162 has completed preclinical and phase 1/2 clinical trials and started phase 2/3 trials in July 2020 (though Pfizer/BioNTech is likely to seek emergency use authorisation in some countries, where it is legally possible, before data from phase 2/3 studies is available).

(b) However, the previous cases relate to influenza vaccines, where the health risks are relatively well understood. The **health risks of COVID-19 vaccines are less clear** because no coronavirus vaccine has been successfully developed before.

This is especially the case for new vaccines types. For example, RNA vaccines like BNT162 have not previously been approved for human use in New Zealand and will require a careful risk-benefit assessment as part of the regulatory approval process.

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

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

13. 9(2)(j)

Scope of the indemnity

14. The indemnity reads:

Appendix A

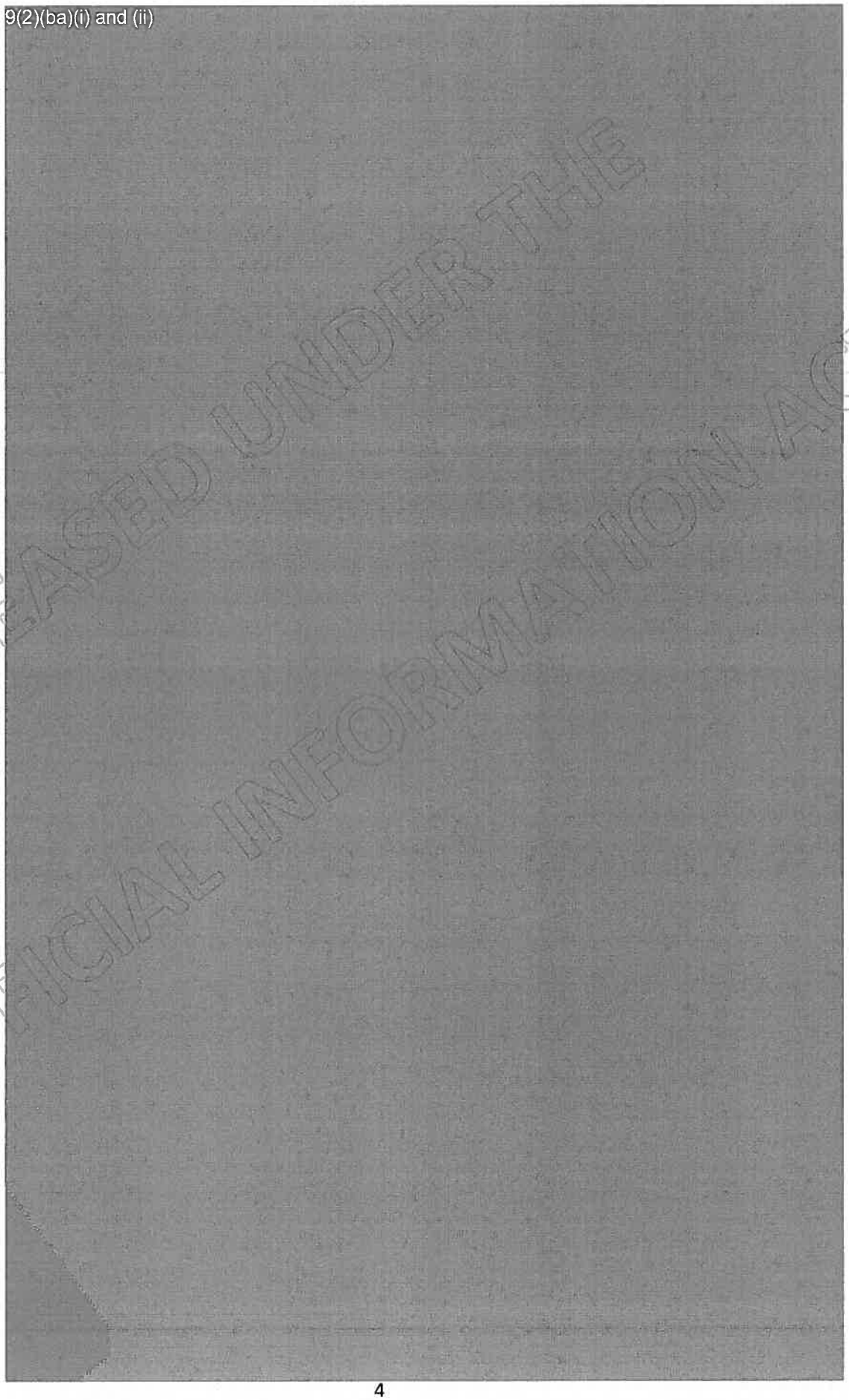
9(2)(ba)(i) & (ii)

INDEMNITY CLAUSE

9(2)(ba)(i) and (ii)

9(2)(ba)(i) and (ii)

9(2)(ba)(i) and (ii)



9(2)(ba)(i) and (ii)

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

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

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

16. A table setting out the differences between this indemnity provision and those previously negotiated in APAs for pandemic influenza vaccine is attached as Annex 2.

9(2)(ba)(i) and (ii)

17. 9(2)(ba)(i) and (ii)

Exposure, risk and mitigation

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

18. ACC can cover personal injuries arising from the administration of a vaccine by a registered medical professional.[3] Costs to ACC related to use of the vaccine in New Zealand will arise regardless of the provision of contractual indemnity.

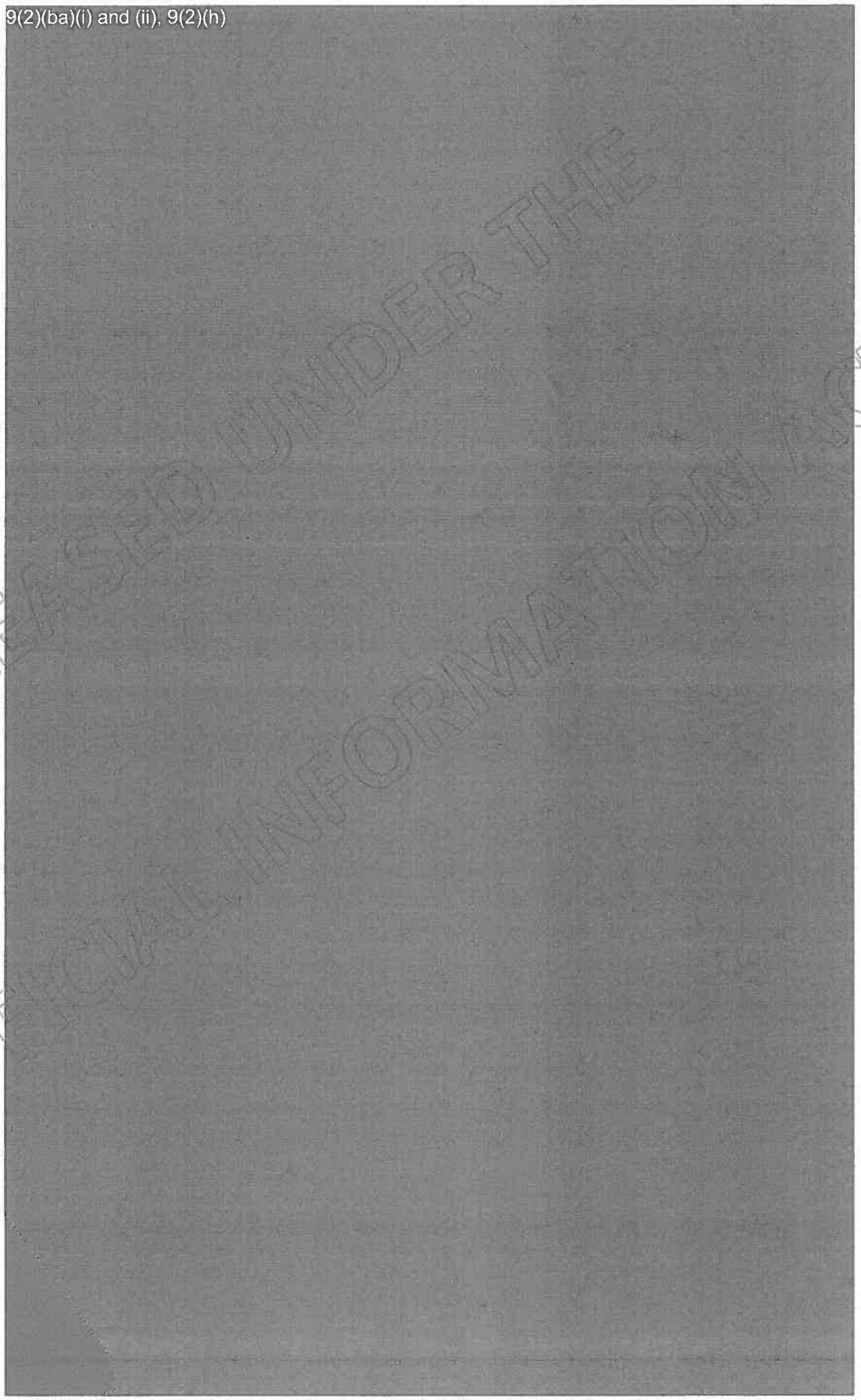
The liability associated with claims not covered by ACC is relatively low-risk

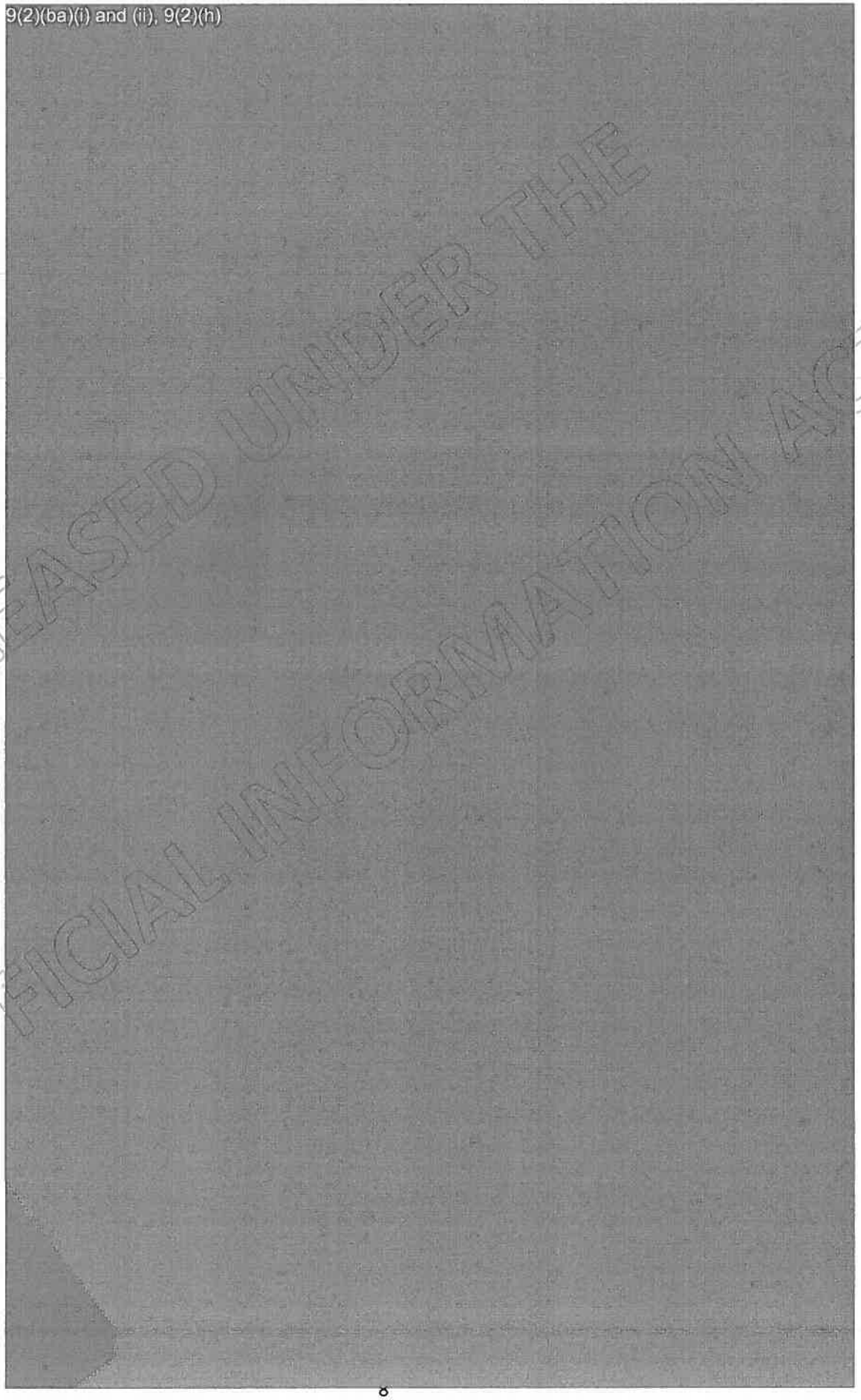
19. Bell Gully has advised that the scope of the indemnity is in practice very close to the scope of ACC (ie personal injury in New Zealand) and that although some risk remains that the indemnity goes beyond what the ACC scheme will cover, for practical reasons the risk to the Crown in this regard is low, and the Crown is able to take certain steps to protect its position as far as possible.

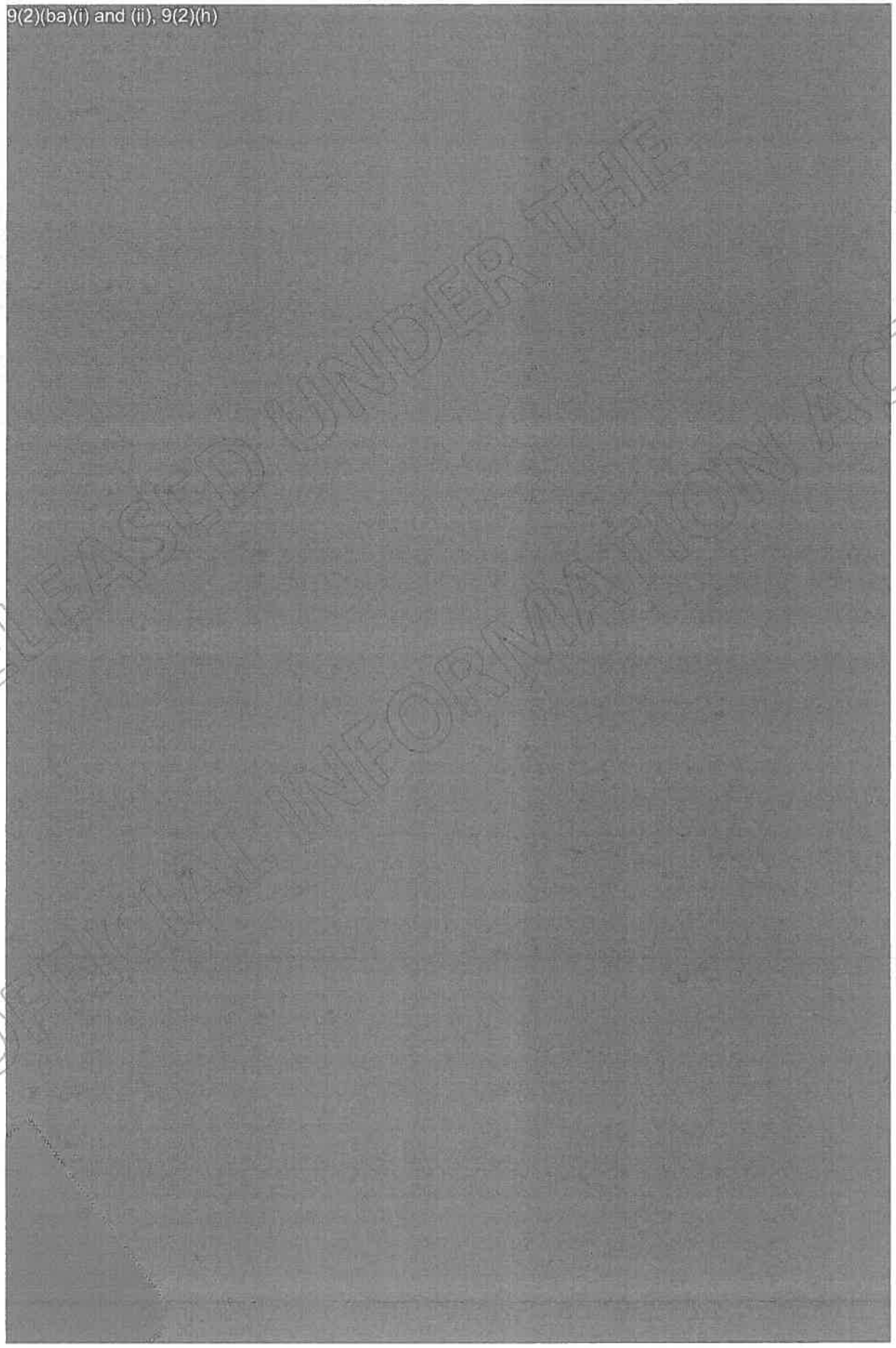
20. 9(2)(ba)(i) & (ii), 9(2)(h)

[3] 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)(ba)(i) and (ii), 9(2)(h)







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

[redacted]

There are measures in place to mitigate the risk of injuries

27. 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 – 9(2)(ba)(i) & (ii) [redacted] – though as noted above, Bell Gully considers these risks to be relatively low.

28. Pfizer is a well-established company in New Zealand with strong capability to distribute, track and recall 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 BNT162 vaccine.
- 9(2)(ba)(i) and (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) and (ii) [redacted]

We are working to mitigate additional risks associated with the indemnity

29. 9(2)(ba)(i) and (ii)

30. A key aspect of our communications and engagement approach is to recognise and 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.

31. 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.

32. 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. We will also consider how to handle media and public questions about the indemnity (noting that the indemnity is likely to be public knowledge because the Minister of Finance is required to publish a Gazette Notice, but Pfizer/BioNTech is likely to require the details of the agreement to be confidential).

33. 9(2)(ba)(i) and (ii)

9(2)(ba)(i) and (ii)

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

38. [redacted]

39. [redacted]

Termination Arrangements

40. 9(2)(ba)(i) and (ii) [redacted]

Necessary or Expedient in the Public Interest

41. 9(2)(ba)(i) and (ii) [redacted]

42. Pfizer/BioNTech's position on indemnity is not unusual. We are aware that pharmaceutical companies are seeking indemnities from other governments for the supply of COVID-19 vaccine. 6(b)(i) [redacted]

43. An APA with Pfizer/BioNTech is not in itself necessary, as we are also negotiating APAs with other pharmaceutical companies for the supply of COVID-19 vaccines.

44. However, our aim is to conclude a portfolio of APAs in order to manage the scientific, commercial and political uncertainties surrounding COVID-19 vaccine development and achieve our Vaccine Strategy objective of ensuring access to a safe and effective vaccine.

45. Agreeing to indemnify Pfizer/BioNTech is expedient because it will help us achieve these objectives in the current circumstances where:

    - Negotiations with different pharmaceutical companies are not taking place simultaneously, so we have imperfect information on the terms and conditions that other companies will seek and cannot make a decision based on the best available offer(s), 9(2)(ba)(i) and (ii) [redacted]
    - We have to move quickly and pragmatically to secure APAs in a fast-moving environment where there is unprecedented global demand.

46. The meaning of "public interest" depends on the circumstances and can be multi-faceted. For example, Black's Law Dictionary (online ed.) defines it as including "The general welfare of a populace considered as warranting recognition and protection." The indemnity is in the public interest because, by helping us achieve the objectives outlined above, it will improve New Zealanders' wellbeing as outlined in the "Benefits" section below.

Benefits to the Crown of the Indemnity

47. The key benefit of the indemnity is that it will allow New Zealand to conclude a bilateral APA with Pfizer/BioNTech, which itself will have the benefits outlined below.

An APA with Pfizer/BioNTech will contribute to our portfolio of APAs for promising vaccine candidates

48. 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 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 the Pacific). 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.

49. 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 the Pacific), with vaccines spread across a number of different platforms, and to obtain early coverage where possible.

50. This vaccine candidate has the advantage of being one of the group expected to have the earliest delivery date, and 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.

51. This vaccine 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) and (ii)

[redacted]

We are also pursuing vaccine candidates based on replicating viral vector and protein subunit technologies.

52. The potential benefit offered by the Pfizer candidate, in relation to the rest of our likely portfolio, is timeliness. 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.

53. 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 the Pacific.

54. Advance purchase arrangements 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 bilaterally, or purchase other candidates to diversify our portfolio. Pfizer have indicated they are in negotiations with the facility.

55. 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.

Access to a safe and effective vaccine would have economic and social benefits for New Zealand

56. The potential economic and social benefits of a vaccine are uncertain. The Ministry of Health is beginning work on economic modelling in this area. The potential benefits depend on many factors including how long and in what population groups the vaccine gives protection, and how and when herd immunity can be achieved.

57. It can be expected that a safe and effective COVID-19 vaccine, widely taken up, could mitigate the impacts of COVID-19 to date by allowing New Zealand to consider moving on from some elements of the current elimination strategy – for example by relaxing border settings – and thereby contribute to economic and social recovery while ensuring the health and safety of New Zealanders.

58. The key impacts of the lockdowns and economic downturn associated with COVID-19 that a vaccine may mitigate are:

Economic impacts

- The Treasury has revised the impact assumptions that alert level restrictions have. At alert level 1, economic activity is believed to be roughly 5% lower than potential. However, this reflects not only the direct impact of international tourism from a closed border, but also the knock-on effects on other sectors due to lower aggregate demand in the economy, as well as the lingering effects of alert levels 2 to 4 on business and consumer confidence. The direct impact of alert level 1 restrictions and the closed border is therefore likely to be lower than this.

- Over time, as some resources are re-allocated away from tourism-facing sectors to other sectors of the economy, the direct impact of alert level 1 on economic activity levels is expected to decline. Furthermore, when border restrictions are removed, 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.

Health impacts

- New Zealand has experienced only a low number of COVID-19 deaths. As of 9 September, there have been 1,788 confirmed and probable cases of COVID-19, of which 1,639 people have recovered and 24 people have died (Ministry of Health, 2020).

- However, the nationwide Level 4 lockdown had some direct health impacts – for example, risk of delayed diagnosis of severe conditions depending on the extent to which the lockdown discouraged people from accessing primary care, and disruption in planned hospital care and outpatient appointments.

An APA with Pfizer/BioNTech gives us the option to provide vaccine to Pacific countries

59. Due to cold chain storage requirements we are unlikely to choose this particular vaccine for delivery in the Pacific. 9(2)(ba)(i) and (ii) [redacted] For completeness, we have set out below the benefits that the provision of vaccine to Pacific countries would have for New Zealand.

60. We are working through the issues that provision of vaccine to Pacific countries would raise, which 9(2)(ba)(i) and (ii) include distribution of vaccine doses, additional support required, ensuring the vaccines are appropriate for the Pacific environment, 9(2)(ba)(i) and (ii) [redacted]

61. The global marketplace for a COVID-19 vaccine is highly competitive, and Pacific Island countries are at risk of falling to the back of the queue (or being offered a sub-standard vaccine). New Zealand supporting Pacific countries to access and deliver a COVID-19 vaccine would demonstrate a strong commitment to partnership with the region, and will deliver significant social, economic and development benefits for the region, while protecting New Zealand's geostrategic interests.

62. In particular, New Zealand has special responsibilities towards Cook Islands, Niue and Tokelau. These arise from the unique constitutional relationship that has developed as part of the decolonisation process. Cook Islands, Niue and Tokelau are all part of the Realm of New Zealand and the Queen in Right of New Zealand is their head of State.

63. The people of Cook Islands, Niue and Tokelau have full New Zealand citizenship (and there is no separate Cook Islands, Niuean or Tokelauan citizenship). The Government of New Zealand has an obligation to protect New Zealand citizens in the Realm and to take account of the vital interests of the Realm.

64. The impact of COVID-19 on the Cook Islands and Niue has been particularly severe – it threatens their economic survival. COVID-19 border settings have had a devastating effect on revenue and constrained the movement of people and delivery of essential services.

65. Providing vaccines to the Pacific Realm will support the vital interests of New Zealand and the Realm which include:

- protecting New Zealand citizens in Realm countries from serious disease and risk to health;
- upholding the rights of New Zealand citizens in Realm countries to travel to New Zealand and to enable Realm countries to re-open their borders;
- The resumption of regular transport connections which are vital for economic and social activity in the Pacific Realm. These links are also critical to sustaining essential commercial, family, and people linkages with New Zealand as well as access to essential services such as health care, education and access to justice (via access to the judiciary), some of which are not available in Realm countries;
- Facilitating the economic recovery of and longer term economic viability of the Cook Islands and Niue (particularly in view of the importance of tourism to their economies).

Overall judgement

66. As noted above, Bell Gully has advised that the scope of the indemnity is in practice very close to the scope of ACC (ie personal injury in New Zealand) and that although some risk remains that the indemnity goes beyond what the ACC scheme will cover, for the practical reasons outlined above the risk to the Crown in this regard is low.

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

Risk Management

68. 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

69. 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

70. We are briefing responsible Ministers in parallel with submitting the business case to the Treasury, in order to conclude the agreement with Pfizer/BioNTech as quickly as possible.

Notification Requirements

71. 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 [insert date that Minister of Finance gives indemnity, once Definitive Agreement is signed] I, Grant Robertson, Minister of Finance, on behalf of the Crown, gave an indemnity in favour of Pfizer/BioNTech in an Advance Purchase Agreement for the supply of BNT162, an mRNA vaccine directed against SARS-COV2 to prevent COVID-19 infection in humans.

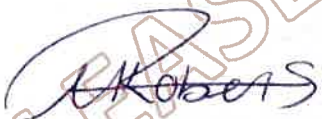
Dated at Wellington this [insert date of month] day of [insert month] [insert year].

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 Pfizer/BioNTech on the terms contained in the Term Sheet in Annex I.

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

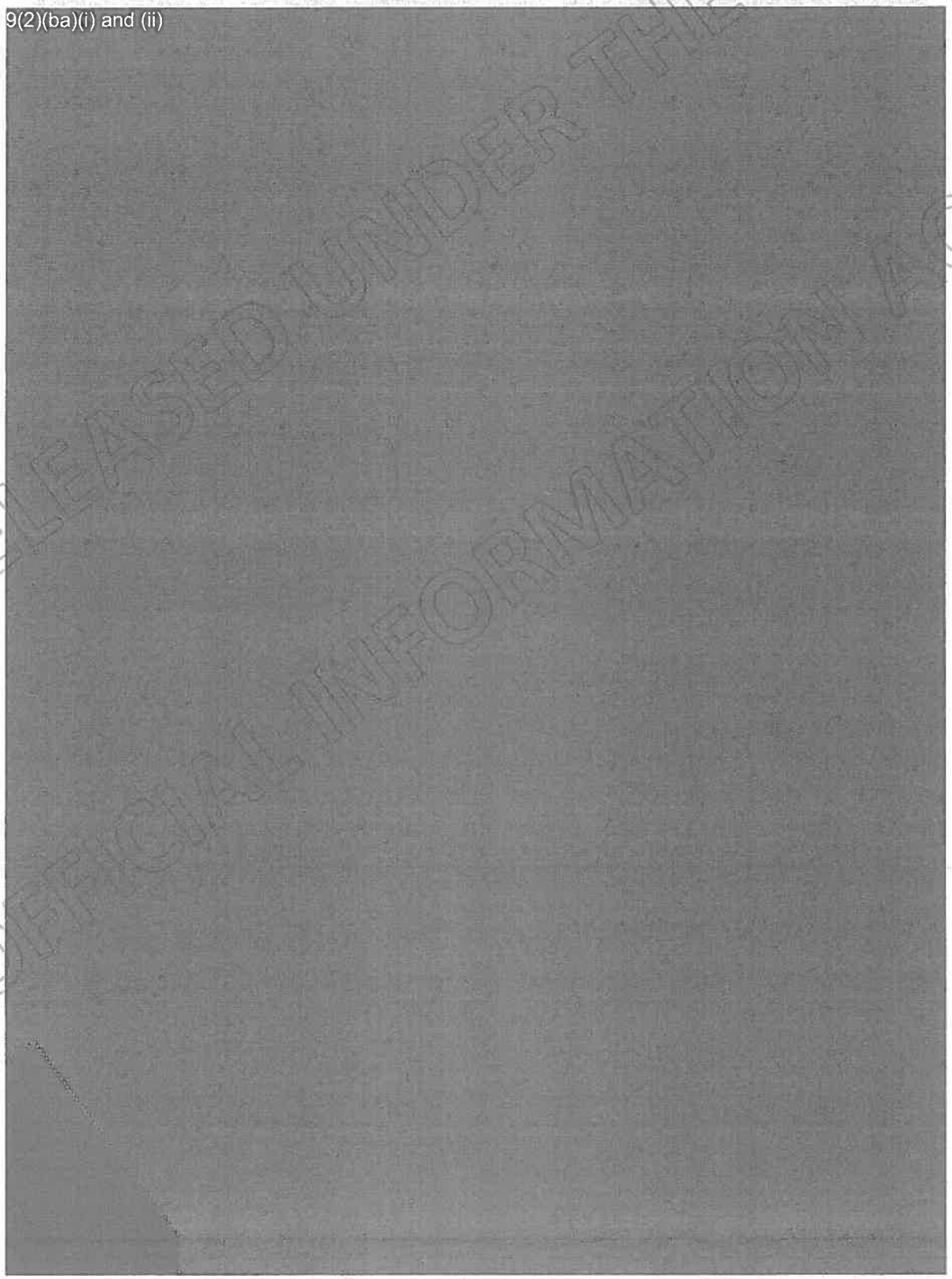


Maree Roberts
Deputy Director-General, System Strategy and Policy
Delegate of Chief Executive
Ministry of Health

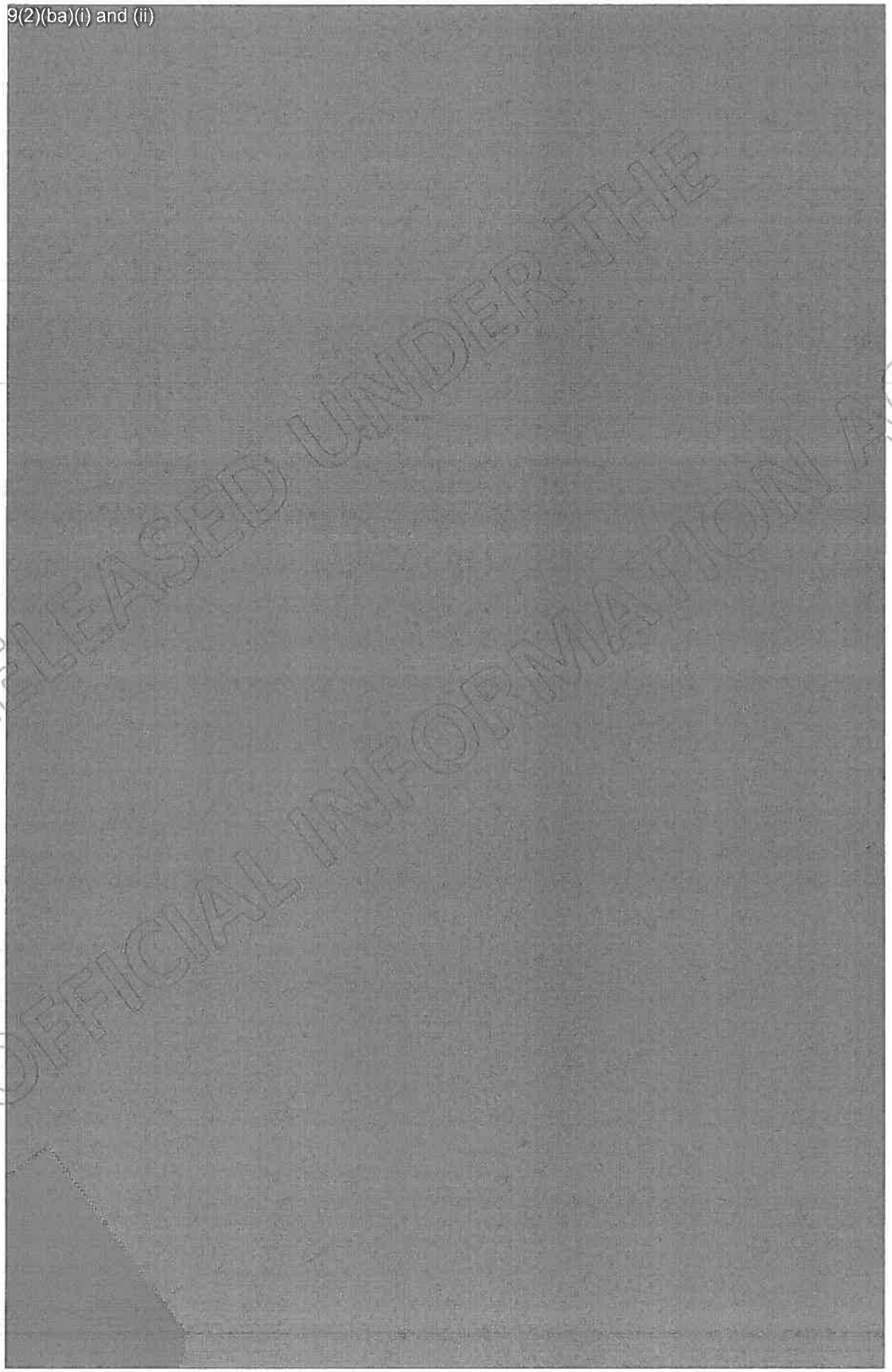
Annex I: Binding term sheet

BINDING TERM SHEET

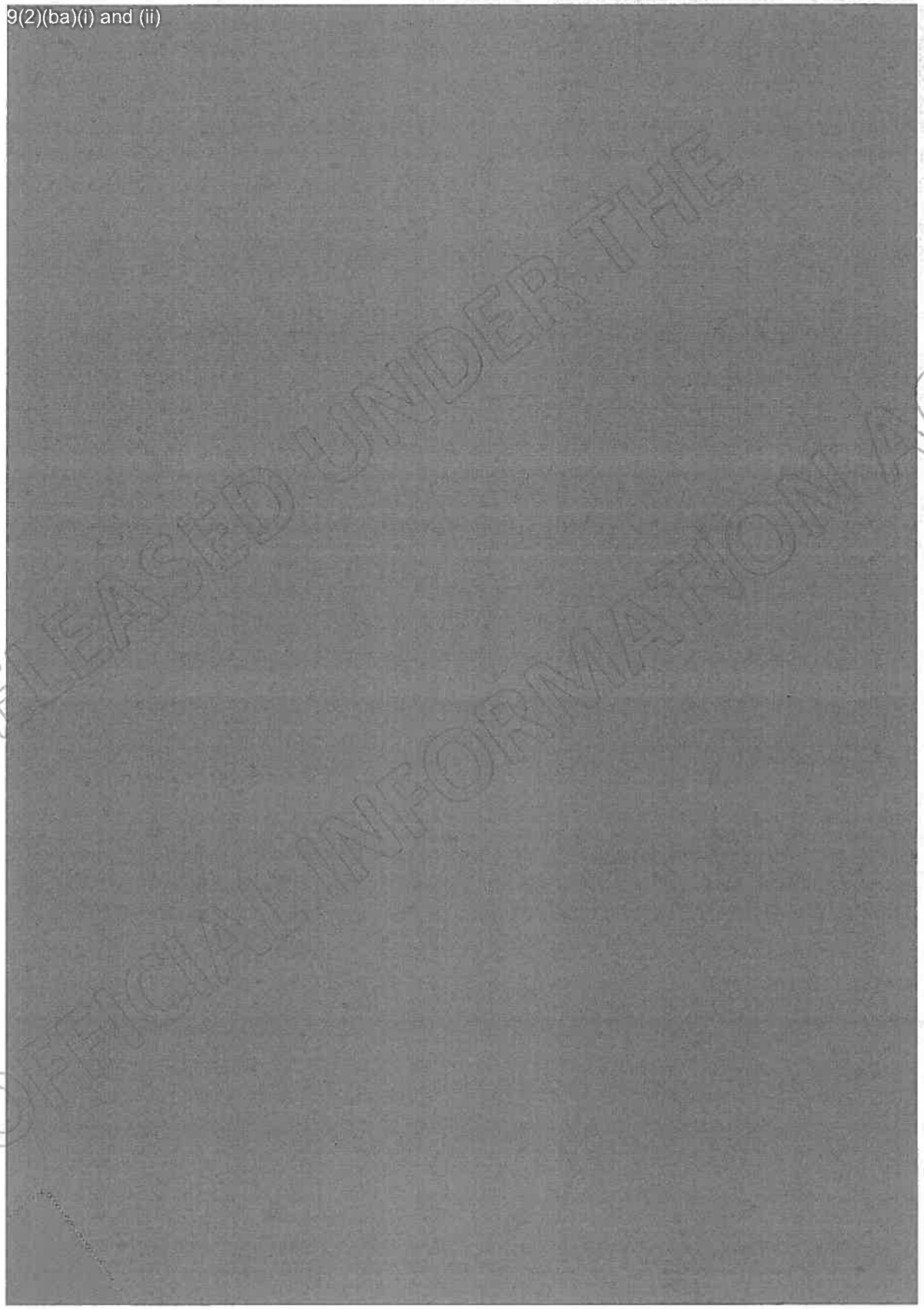
9(2)(ba)(i) and (ii)



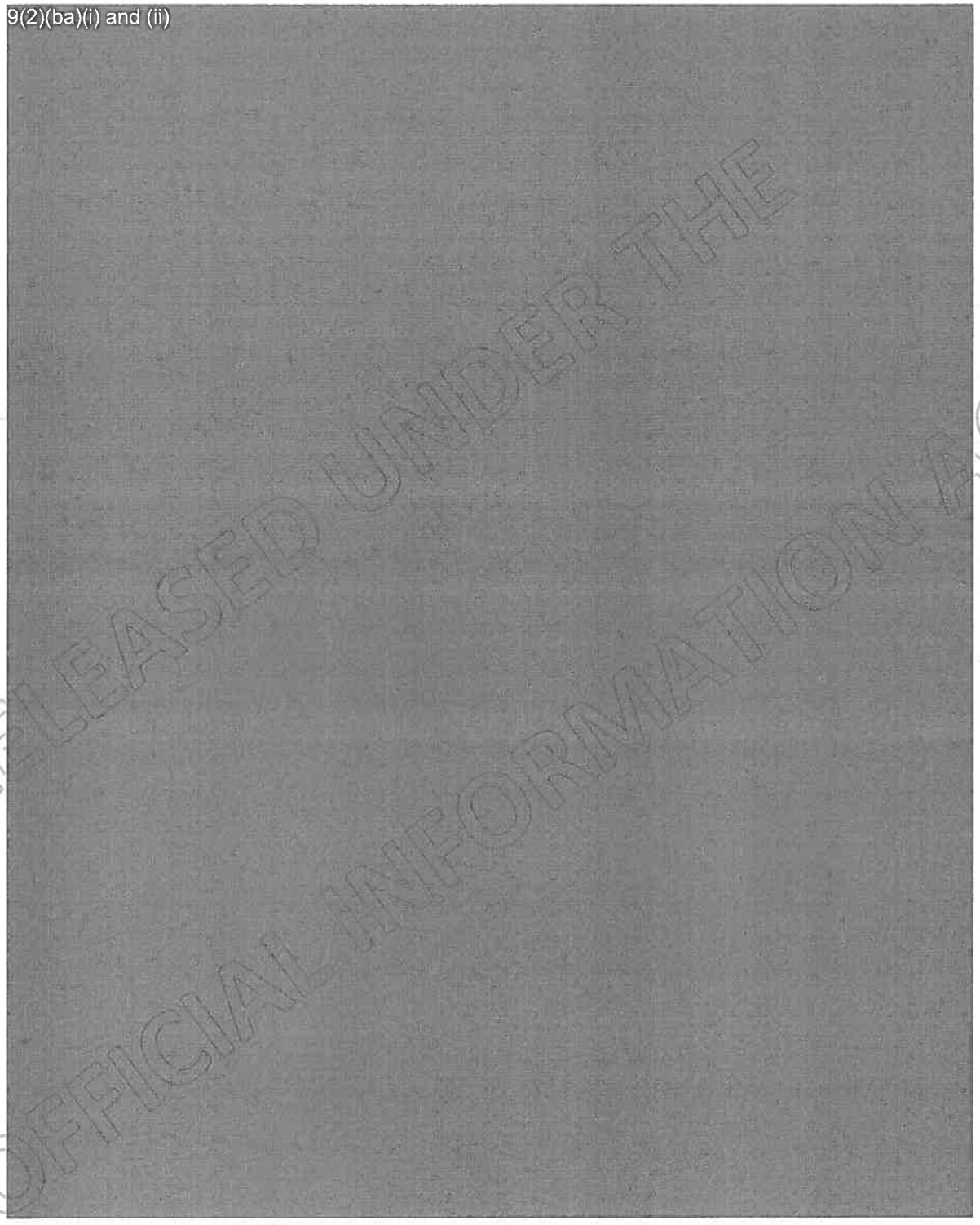
9(2)(ba)(i) and (ii)



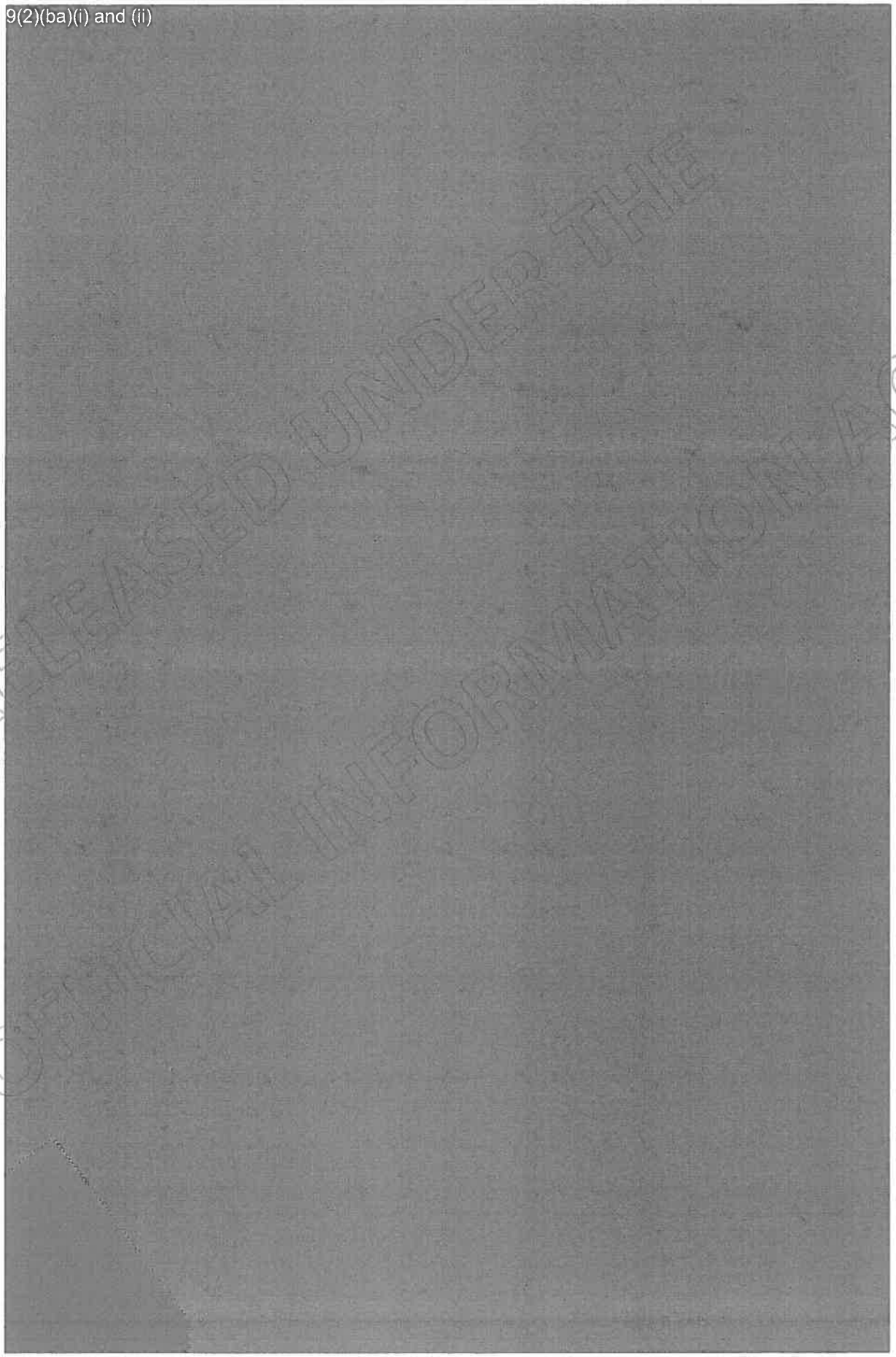
9(2)(ba)(i) and (ii)



9(2)(ba)(i) and (ii)



9(2)(ba)(i) and (ii)



9(2)(ba)(i) and (ii)

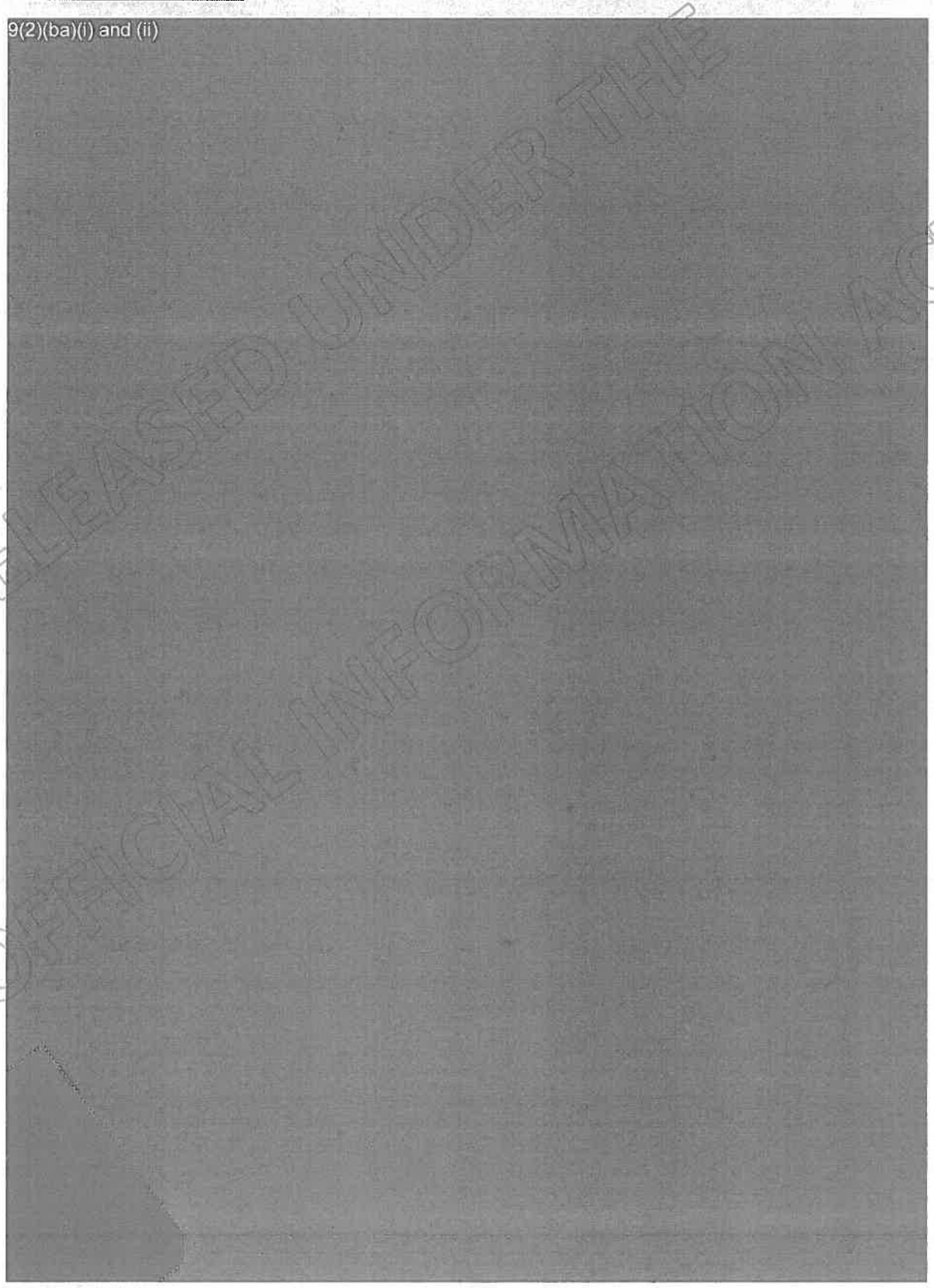
SIGNED for and on behalf of **Pfizer Inc**	SIGNED for any on behalf of **the Sovereign in Right of New Zealand acting by and through the Director-General of the Ministry of Health (or their authorised delegate)**
Name:	Name:
Position:	Position:
Signature:	Signature:
Date:	Date:

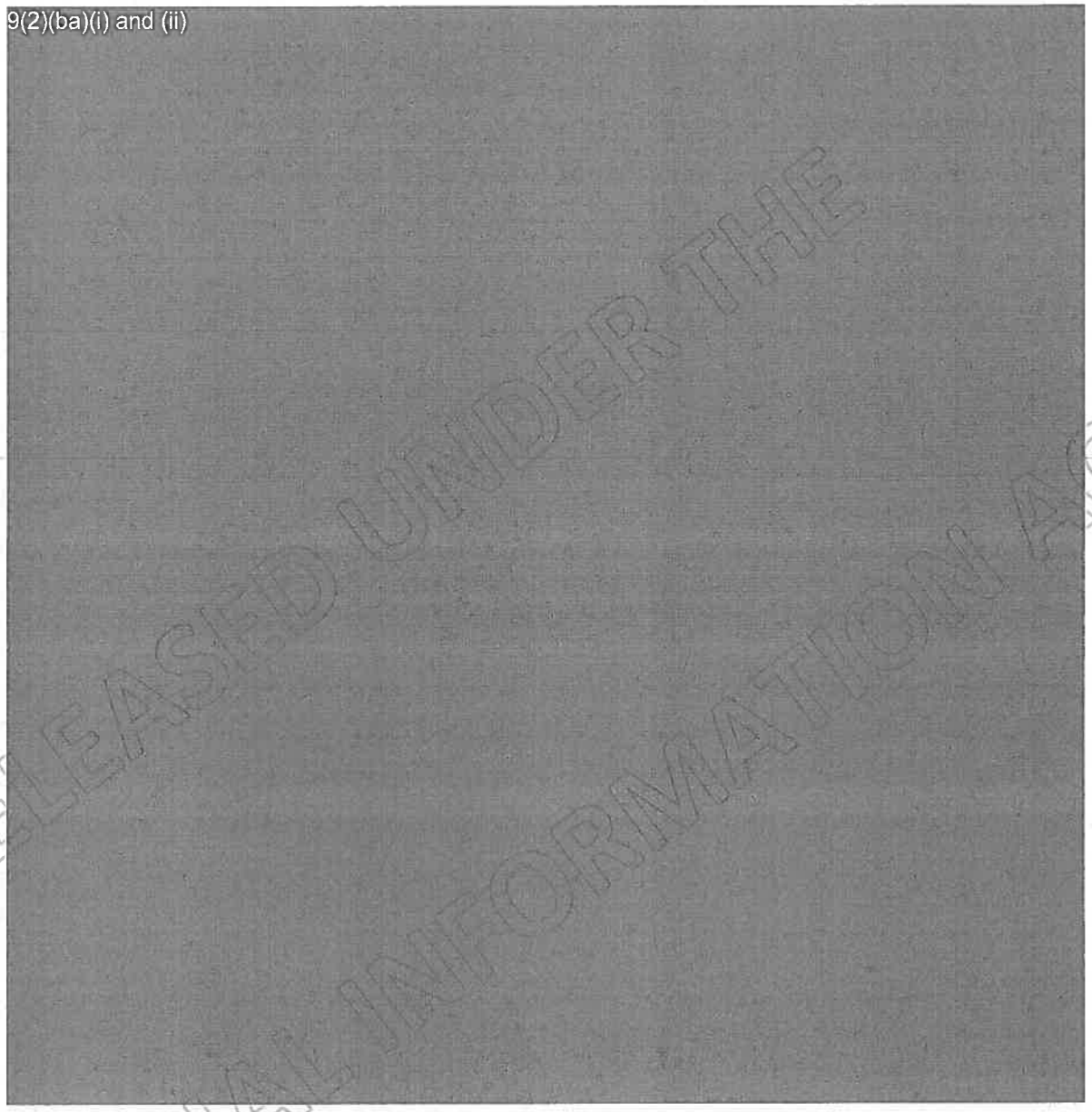
Appendix A

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

INDEMNITY CLAUSE

9(2)(ba)(i) and (ii)





Annex 2: Indemnities comparison