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

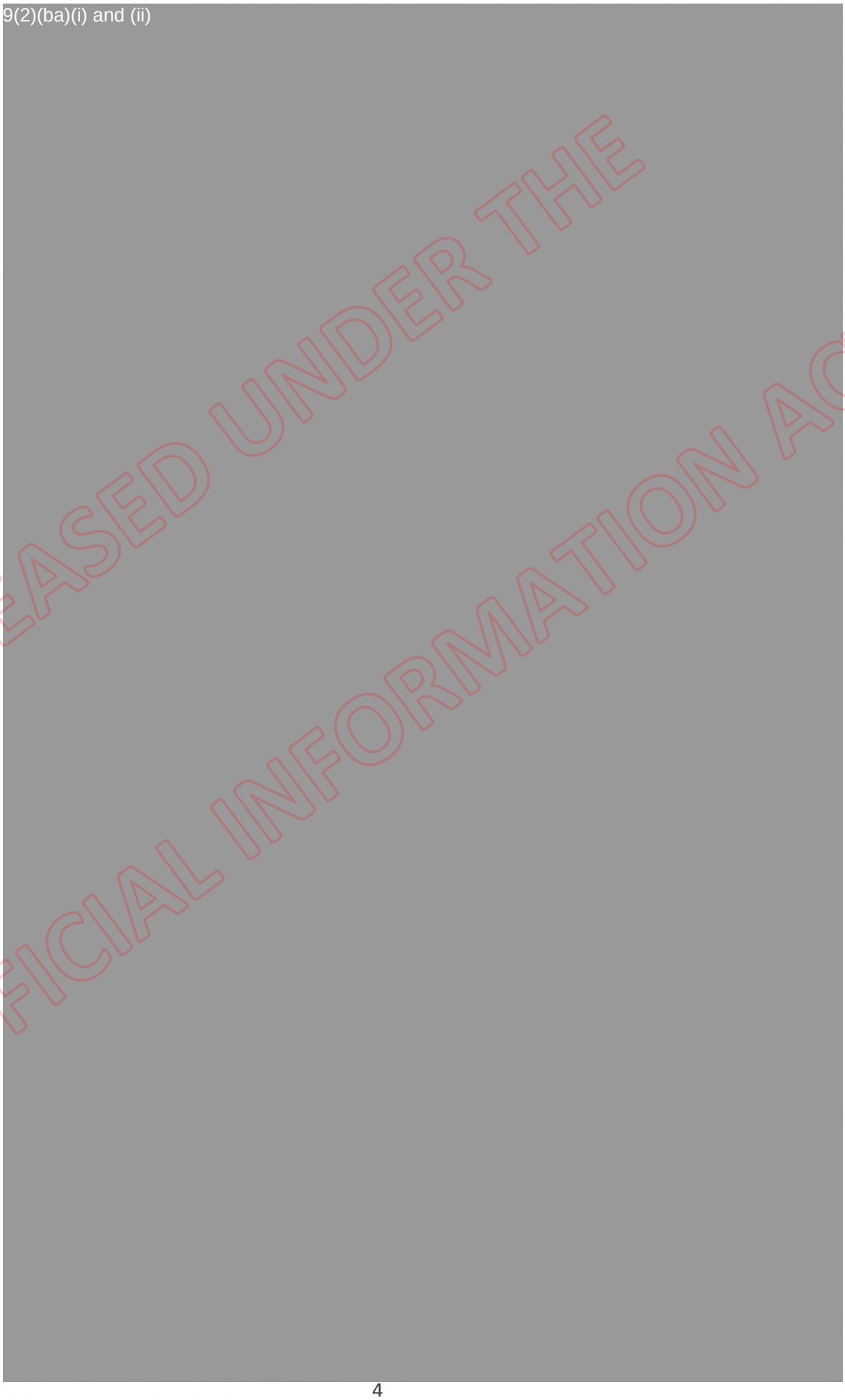
9(2)(ba)(i) & (ii)

INDEMNITY CLAUSE

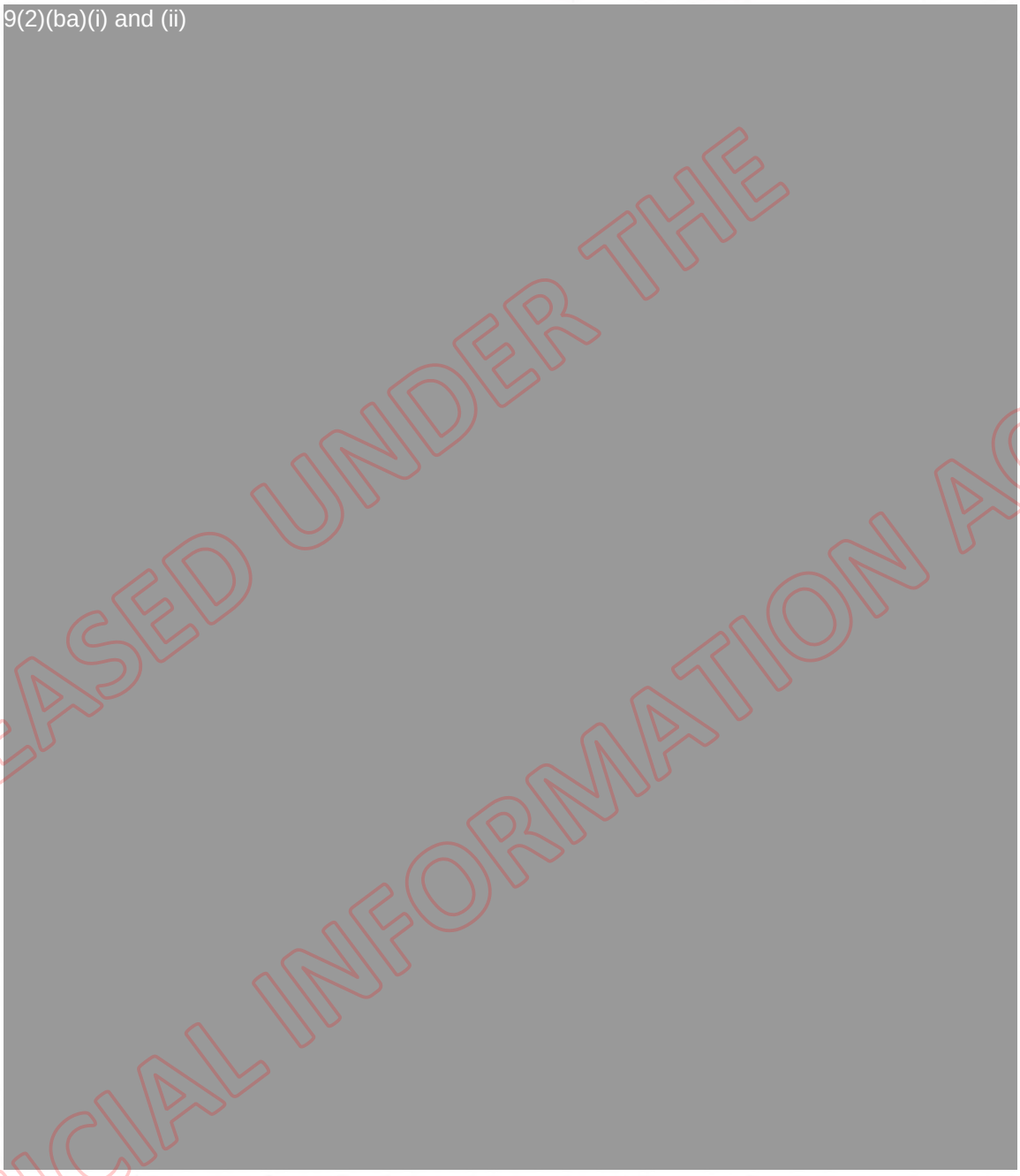
9(2)(ba)(i) and (ii)

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.

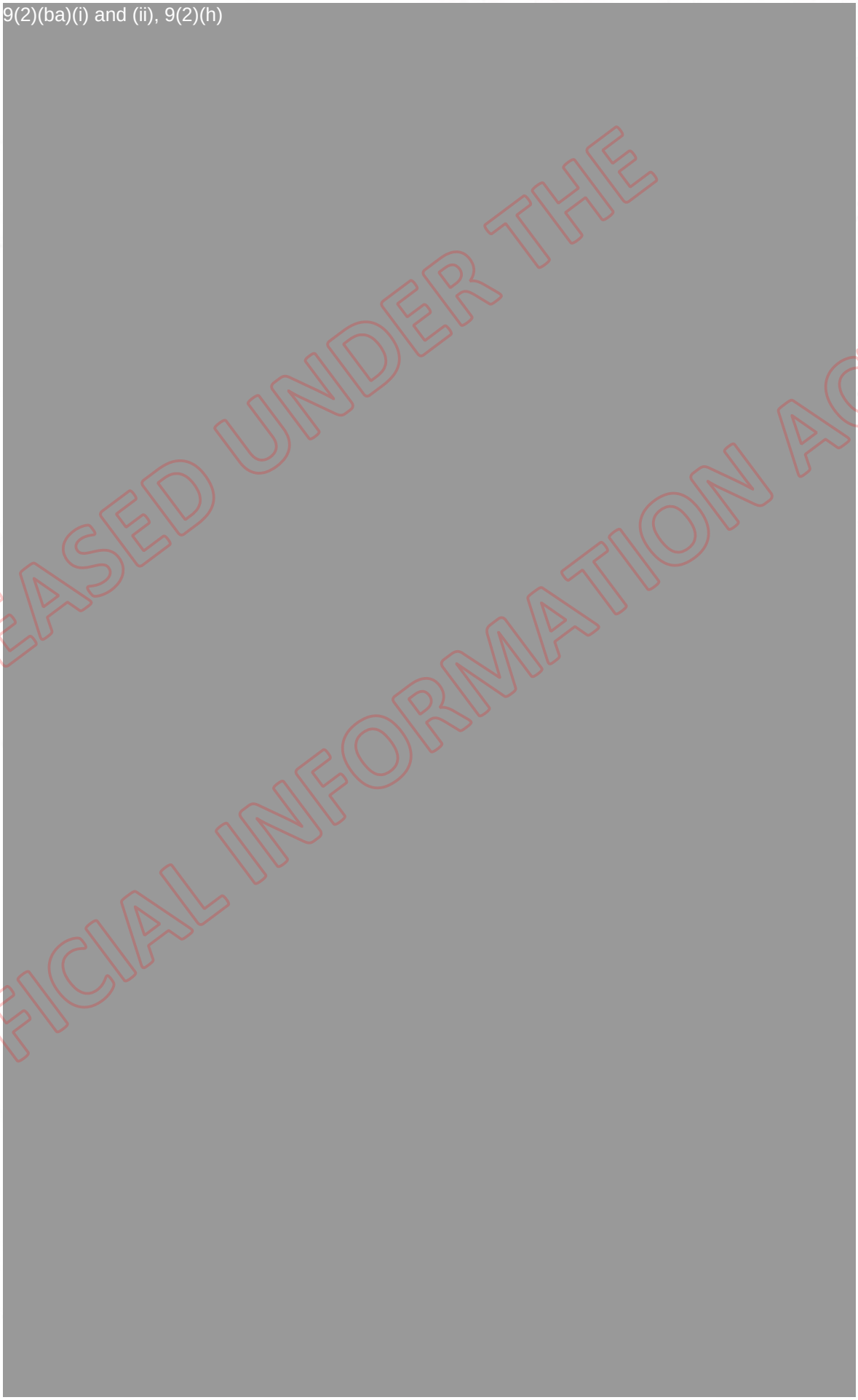
The liability associated with claims not covered by ACC is relatively low-risk

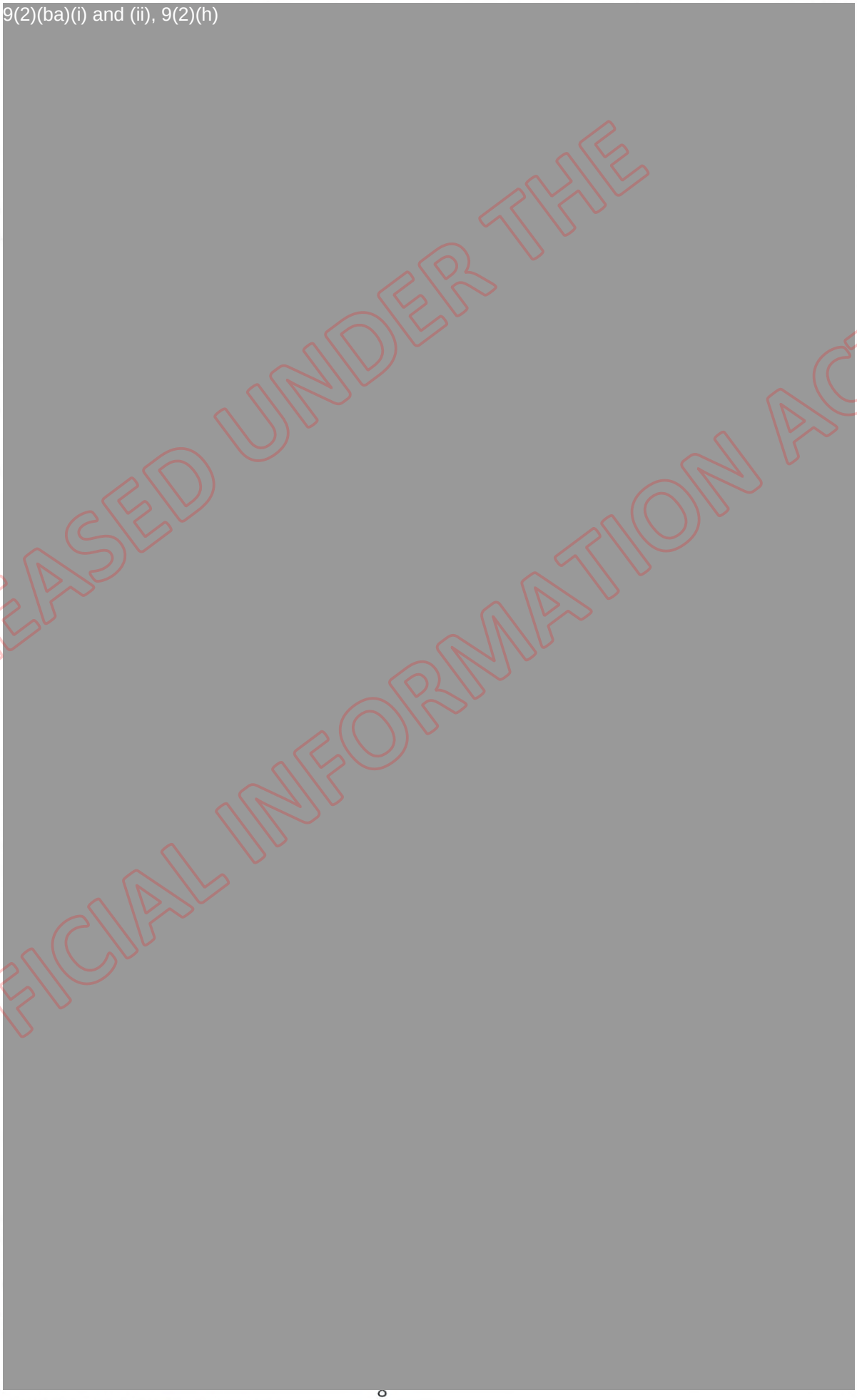
19. Bell Gully has advised that the scope of the indemnity is in practice very close to the scope of ACC (ie personal injury in New Zealand) and that although some risk remains that the indemnity goes beyond what the ACC scheme will cover, for practical reasons the risk to the Crown in this regard is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

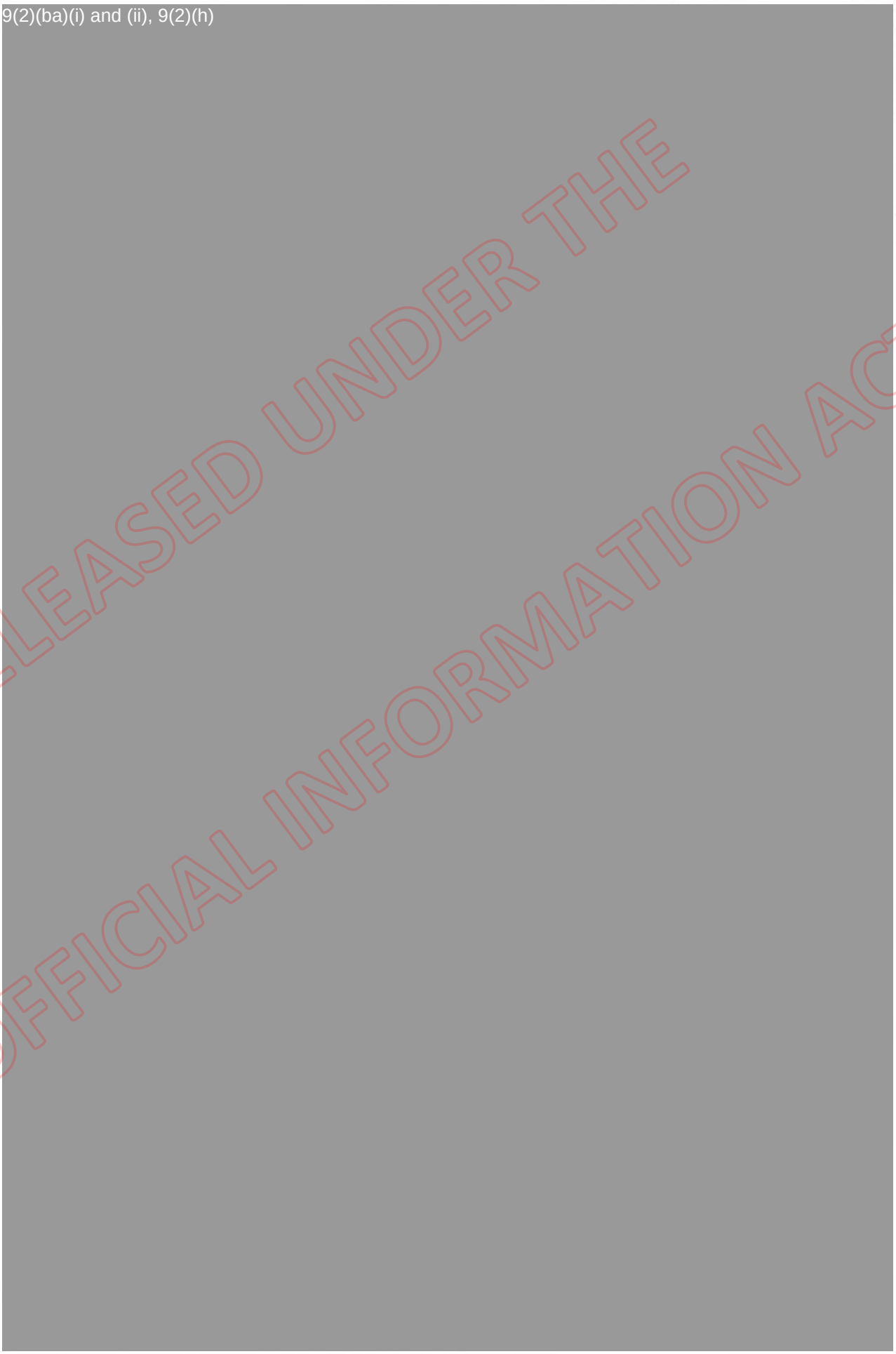
20. 9(2)(ba)(i) & (ii), 9(2)(h)

[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)

38.

39.

Termination Arrangements

40. 9(2)(ba)(i) and (ii)

Necessary or Expedient in the Public Interest

41. 9(2)(ba)(i) and (ii)

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)

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.

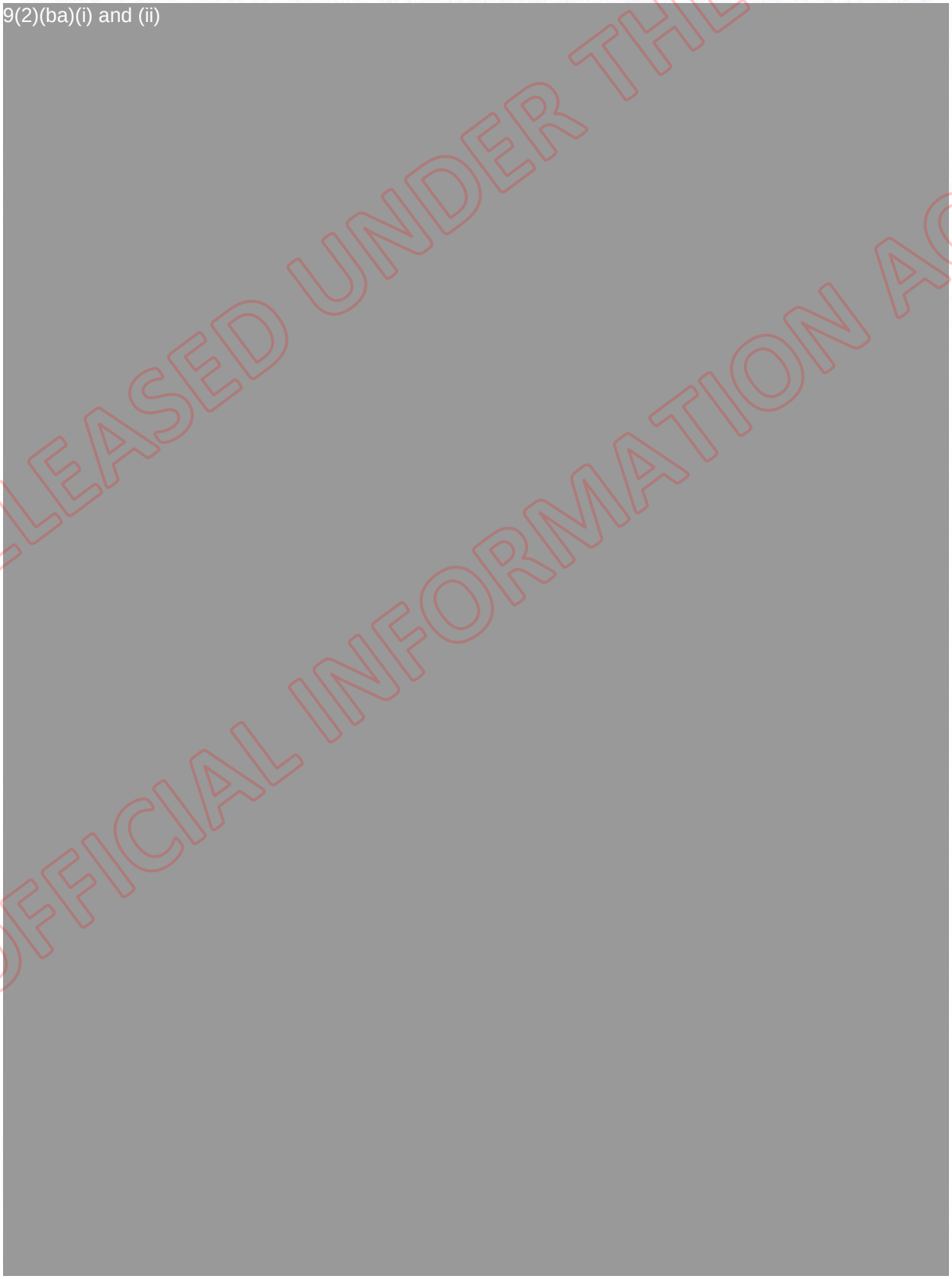
Peter Crabtree
Delegate of Chief Executive, Carolyn Tremain
Ministry of Business, Innovation and Employment

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

Annex I: Binding term sheet

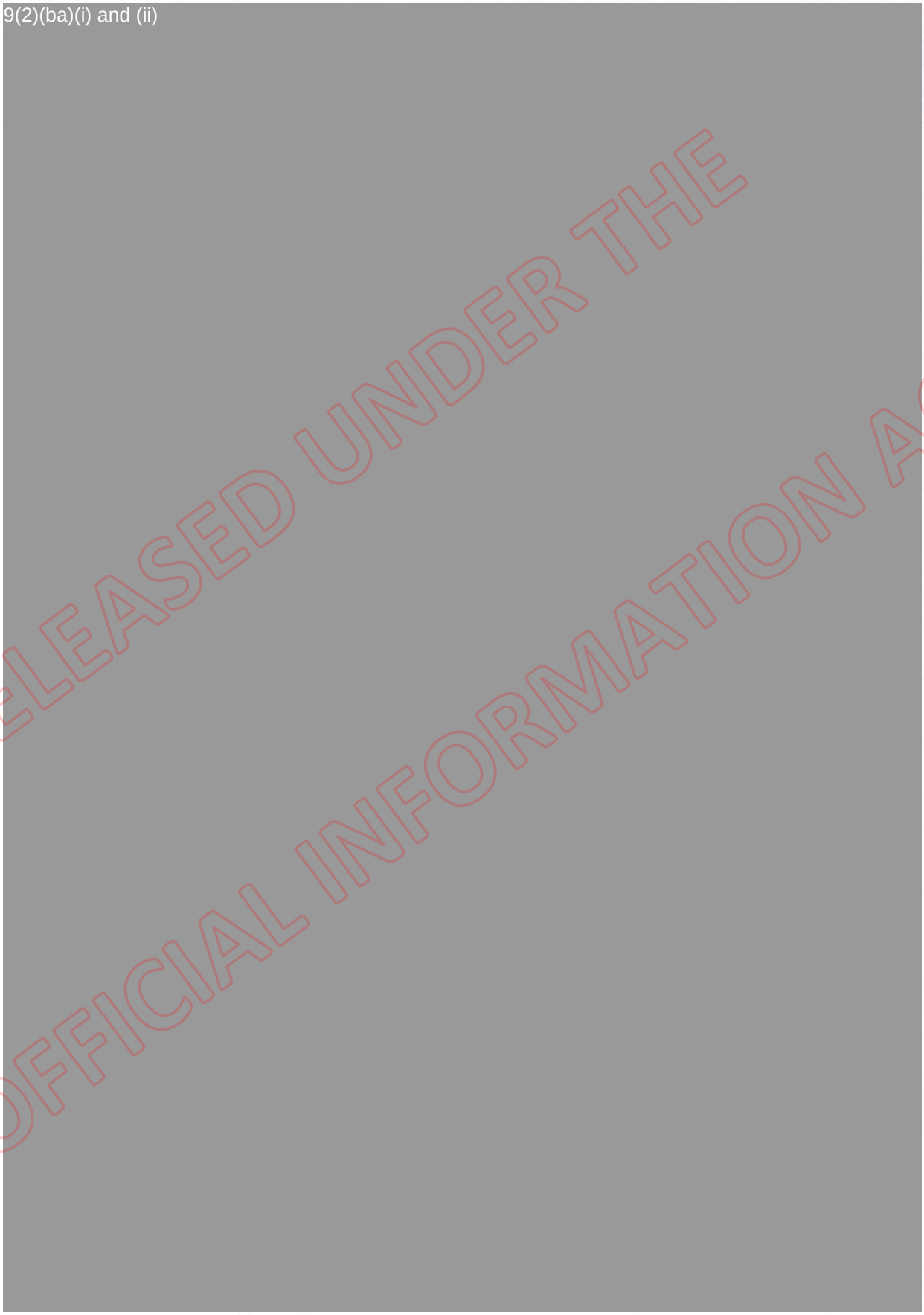
BINDING TERM SHEET

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)

SIGNED for and on behalf of
Pfizer Inc

Name:

Position:

Signature:

Date:

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:

Position:

Signature:

Date:

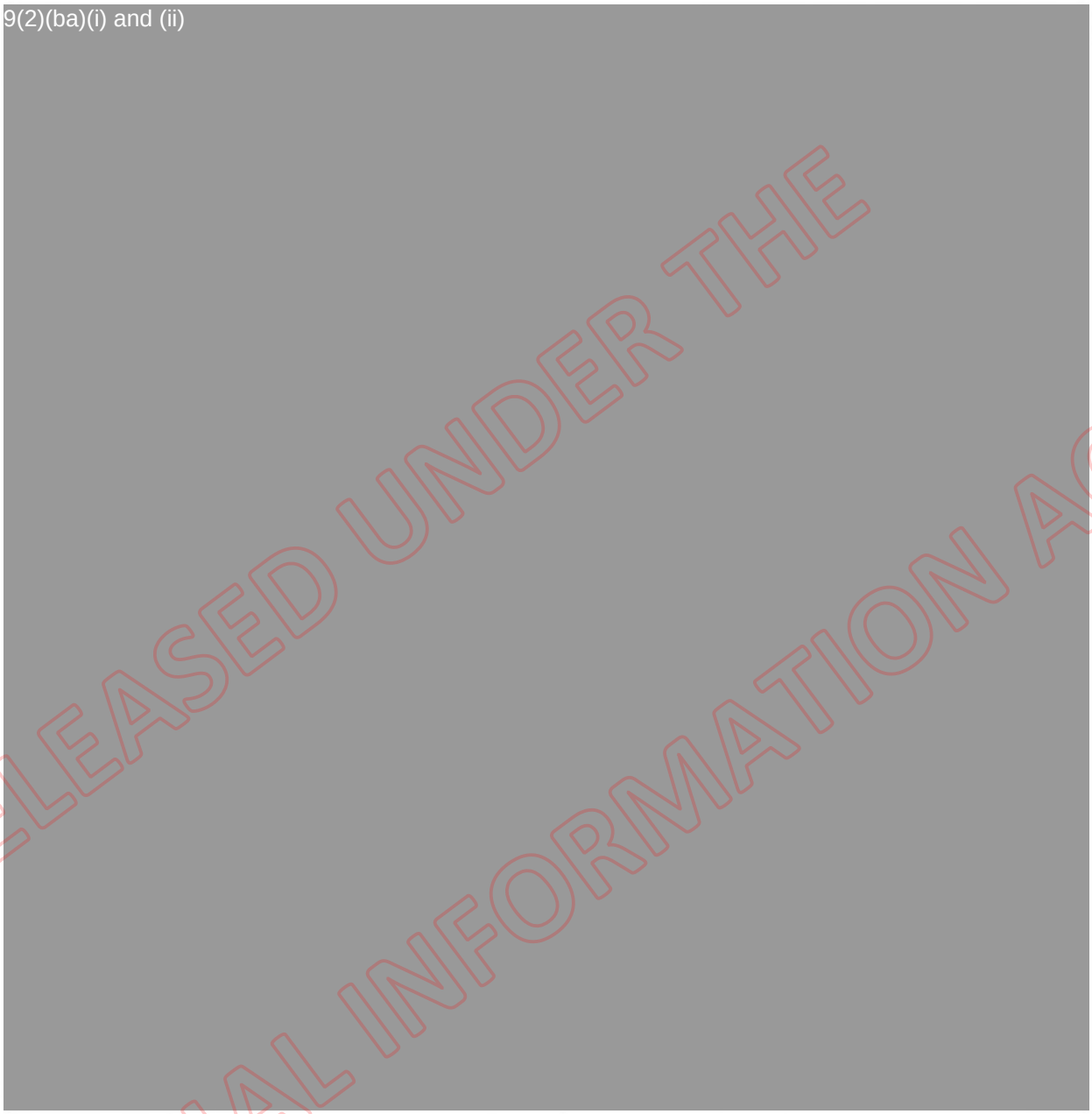
Appendix A

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

INDEMNITY CLAUSE

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

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



Annex 2: Indemnities comparison