Hon Nicola Willis

Minister of Finance
Minister for the Public Service
Minister for Social Investment
Associate Minister of Climate Change

26 February 2024

M Bell
fyi-request-25344-958bdd35@requests.fyi.org.nz

Dear M

Thank you for your Official Information Act (OIA) request, received on 7 January 2024. You requested:

> *On page 2 of the MBIE Pfizer Indemnity Business Case, signed off by the then Minister of Finance it is stated that ...*
>
> *"The Minister of Finance has given an indemnity in relation to influenza vaccine on four occasions:*
> *o A 2016 APA with Seqirus Ltd (previously bioCSL and CSL), renewing a 2005 APA with CSL for the supply of H5N1 pre-pandemic vaccine o A 2009 APA with Baxter Healthcare Ltd for supply of pandemic flu vaccine o A 2007 contract with Baxter Healthcare Ltd for the supply of 100,000 vaccination courses of H5N1 non-pandemic vaccine."*
>
> *My request is, please provide those four documents.*

On 12 February 2024, I extended the timeframe on the request by 10 working days.

I understand that following a substantial search, Treasury officials were unable to find a copy of the second document you have requested, '*a 2005 APA with CSL for the supply of H5N1 pre-pandemic vaccine*', on their electronic records. This document is consequently refused under section 18(e) of the OIA, as the document alleged to contain the information requested does not exist or, despite reasonable efforts to locate it, cannot be found. However, I have included an additional document, '*Draft Pandemic Vaccine Risk Management – Indemnity"* from 2005 that sets out additional vaccine indemnity detail.

Information being released

Please find enclosed the following documents:

Item	Date	Document Description	Decision
1.	2005	Draft Pandemic Vaccine Risk Management - Indemnity	Release in full
2.	21 May 2007	Treasury Report T2007/759: H5N1 non-pandemic vaccine purchase – provision of indemnity for the vaccine manufacturer	Release in part
3.	1 June 2009	Deed of Indemnity between the Crown and Baxter Healthcare Limited	Release in part

I have decided to release the relevant parts of the documents listed above, subject to information being withheld under one or more of the following sections of the Official Information Act, as applicable:

- section 9(2)(b)(ii) - protect information where the making available of the information would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information, and
- section 9(2)(ba)(ii) – to protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information would be likely otherwise to damage the public interest.

Information to be withheld

There are additional documents covered by your request that I have decided to withhold in full under the following sections of the OIA, as applicable:

- section 9(2)(b)(ii) - protect information where the making available of the information would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information,
- section 9(2)(ba)(ii) – to protect information which is subject to an obligation of confidence or which any person has been or could be compelled to provide under the authority of any enactment, where the making available of the information would be likely otherwise to damage the public interest, and
- section 18(e) as the document alleged to contain the information requested does not exist or, despite reasonable efforts to locate it, cannot be found *(in reference to document 4)*.

Item	Date	Document Description	Decision
4.	2005	A 2005 APA with CSL for the supply of H5N1 pre-pandemic vaccine	Withhold in full
5.	2017	Deed of Agreement for Supply of Influenza Vaccine between the Crown and Seqirus Pty Ltd (*this is the document referred to in the request as the 2016 APA*)	Withhold in full

In making my decision, I have considered the public interest considerations in section 9(1) of the Official Information Act.

This reply addresses the information you requested. You have the right to ask the Ombudsman to investigate and review my decision.

Yours sincerely

Hon Nicola Willis
Minister of Finance

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Pandemic Vaccine Risk Management - Indemnity

Purpose

The purpose of this paper is to provide background on risk to the Crown regarding acceptance of indemnity for the manufacturer of a pandemic vaccine for use in New Zealand in the event of influenza pandemic.

Executive Summary

1. The risk of significant mortality and morbidity from an influenza pandemic is considered to be high.

2. A pandemic influenza vaccine would be likely to provide a considerable benefit to a large proportion of the population in the event of an influenza pandemic[1].

3. New Zealand is considering entering into a contract to secure supply of an influenza pandemic vaccine in the event that an influenza pandemic occurs. The primary supplier is likely to be Commonwealth Serum Laboratories Ltd. (CSL).

4. Past experience with influenza vaccine indicates that risks from adverse effects are small.

5. Efficacy and safety of the vaccine will be substantially managed by CSL through manufacture and testing of a prototype vaccine that will form the basis of a pandemic vaccine. The prototype is based on the H5N1 virus.

6. Other risks include litigation from:an individual or individuals who does not not receive vaccine when it is available in the country, or who receive vaccine and are not provided with immunity.

7. CSL accepts no liability for use of their pandemic influenza vaccine.

8. Consent forms will be able to cover off risk of immediate adverse effects and known risks.

9. The liability to the Crown is in the context of an emergency response to a global influenza pandemic.

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1 At a rate of 70-90% effectiveness in illness prevention this means between 2,800,070 and 3,600,090 people would be likely to be protected from illness (An Evaluation of the Free Influenza Vaccination Programme Baker, Simon Ministry of Health: Auckland March 2001).

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Risk Identification

There are three identified risks in a pandemic vaccine supply programme. The first is the possibility of adverse reactions. The second and third risks are: the ability to ensure vaccine efficacy, and the ability to provide the vaccine to all those who wish to be immunised in time to provide protection from illness..

Adverse reactions

Assessment of adverse reactions and efficacy of a pandemic influenza vaccine must be based on data from current influenza vaccine. The pandemic influenza vaccine would be an inactivated influenza virus type, currently in use in many countries, so there is an experience base for the assessment of risk.

Adverse reactions to inactivated influenza vaccine are uncommon. Immediate adverse reactions are usually due to the patient having a known anaphylactic hypersensitivity to eggs or other vaccine components. This occurs at a rate of about 1:10,000 and would be able to be avoided in most cases.

Fever, malaise, and myalgia occur infrequently following vaccination. Hypersensitivity is very rare. Guillian-Barre syndrome (GBS) was associated with swine influenza vaccine, but the increased risk associated with other influenza vaccines – if such risk exists – is small, perhaps one additional case per million persons vaccinated. Despite the common misconception that one can get influenza from the vaccine, the inactivated vaccine contains no viable virus and does not cause respiratory symptoms[2].

The only recent known adverse effects related to inactivated virus vaccines are conjunctivitis in some recipients of a Canadian vaccine.

The risk of the vaccine having a long-term adverse effect cannot be known or quantified. However no long-term adverse effects have been identified with current (seasonal) influenza vaccines.

Contraindications

There are very few contraindications to vaccination against influenza. Vaccine should not be administered to persons with known anaphylactic hypersensitivity to eggs or other vaccine components, as described in the package inserts. In the setting of a pandemic, appropriate allergy evaluation and desensitization may be an option for those at particularly high risk of influenza or its complications.

[2] Pain and tenderness at the vaccination site occurs in 10-15% of those vaccinated, and fever and malaise in 1-2%.

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Efficacy and ability to deliver

Efficacy of a vaccine depends on matching the vaccine to the viral strain. It is likely that two doses of a pandemic influenza vaccine will be required to ensure immunity. This provides logistical challenges to include tracking and recall of people for their second vaccination. Vaccine would arrive in New Zealand incrementally, and the Ministry of Health is currently working on policies to enable prioritisation and rapid roll out of the pandemic vaccine.

It is likely that recent experience in the Mennz B vaccination programme would provide a basis for planning systems that could enable another national vaccine programme. In addition, demand for the vaccine is likely to be high given the risk of contracting influenza during a pandemic.

Risk Mitigation

Safety and Efficacy

Formulation of the CSL vaccine is endorsed by the WHO, Australian Influenza Vaccine Committee, and the New Zealand Ministry of Health. CSL will be developing a prototype vaccine over the next four years. This vaccine will be tested in clinical studies.

The outcome of a phase I Clinical study early in 2006 will provide guidance as to the optimal pandemic vaccine formulation for a final clinical trial. The prototype formulation will be selected according to safety and the level of immunity provided. The final prototype pandemic vaccine will be registered and would form the basis of a pandemic vaccine able to be quickly developed on the recognition of a pandemic influenza strain.

Should a pandemic occur before the completion of trials, CSL would utilise the current formulation to develop a pandemic vaccine.

Informed Consent

Informed consent will be required before individuals receive the vaccine, and consent forms can cover a degree of liability risk.

World Health Organisation Support

WHO will offer support in the coordination of clinical trials of prototype vaccine. These trials will determine the amount of vaccine and number of doses required to provide protection, including in different age groups.

As part of its influenza pandemic preparedness plans, WHO also has in place procedures for making specific recommendations to vaccine manufacturing companies and licensing agencies for the composition and approval of a vaccine during an influenza pandemic.

Monitoring and Evaluation

Vaccine effectiveness and safety need to be monitored. While efficacy and safety are important at all phases of vaccine supply, evaluation is particularly important during the earliest stages of vaccine use. Results of efficacy studies may lead to modifying recommendations to optimize vaccine dosing or schedules. Vaccine safety monitoring can identify any unexpected and/or serious adverse events, help guide development of educational efforts and key communication messages and materials, and assure program acceptability. New Zealand will be in a position to benefit from the experience of pandemic vaccine use in Australia and other Northern Hemisphere countries. Guidance on any adverse reactions will be available through the WHO.

Vaccination Plan

The Ministry of Health is currently reviewing and updating the pandemic plan. Pandemic influenza vaccination issues are part of the planning programme, with outputs prioritized for early – mid 2006. Pandemic vaccine programme planning will assume a 2-dose schedule for all recipients.

Planned vaccination strategies will be flexible and responsive not only to vaccine supply but also to the epidemiology of the pandemic. Epidemiological investigations early during the pandemic will be important to help guide decision-making, for example, determination of the groups that are at highest risk for adverse health outcomes and the age-specific case-fatality rate.

National surveillance for adverse events following immunization is routinely conducted through the Centre for Adverse Monitoring at the New Zealand Pharmaco-vigilance Centre. Health care providers report adverse events that may be associated with vaccination. Reports of serious adverse events are followed up to collect additional information for analysis to determine whether such events are reported more frequently than expected. Signals of potential vaccine-associated events are analyzed for biological plausibility and may lead to specific epidemiological studies to further assess possible causation. The Ministry of Health is currently investigating the feasibility of enhancing current systems for use in a pandemic. .

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Summary

In the event of an influenza pandemic, use of pandemic vaccine would be justified according to the risk-benefit approach that must be taken. The risk of significant mortality and morbidity from a pandemic is considered to be high. Should a pandemic occur a vaccine would be likely to provide a considerable benefit to a large proportion of the population.

Extensive historical data related to influenza vaccine safety is available. Comprehensive pre-release testing for rare adverse effects in a new pandemic vaccine would require thousands of subjects and would take up time and resources that would be in short supply during a pandemic. Consideration is being given on how current systems for surveillance and monitoring of adverse effects could be augmented for real time assessment of a pandemic vaccine testing. Testing and registering of the prototype vaccine by the manufacturer and support and advice from the WHO provides a degree of surety of safety and efficacy.

Acceptance of indemnity by the Minister of Finance for use of pandemic influenza vaccine will carry some risk. The actual amount of fiscal risk is difficult to quantify. In the wider context the benefit of having a vaccine available for the general population, as early as possible in the pandemic, is likely to be significant.

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DEED OF INDEMNITY

THIS DEED is made the day of 2007

BY **HER MAJESTY THE QUEEN** in right of New Zealand acting by and through the **MINISTER OF FINANCE** ("the Crown")

IN FAVOUR OF **BAXTER HEALTHCARE S.A.**, having its registered office at Baxter Healthcare S.A., Hertistrasse 2, 8304 Wallisellen, Switzerland ("Baxter Healthcare")

BACKGROUND

A. The Crown acting by and through the Director-General of the Ministry Health is entering into an agreement for the supply of 200,000 doses of H5N1 non-pandemic vaccine ("the Agreement");

B. Under clause 14.6 of the Agreement, Baxter Healthcare requires that the Crown provide an indemnity in favour of Baxter Healthcare in the terms set out in the Schedule to this Deed ("the Indemnity"); and

C. Under section 65ZD of the Public Finance Act 1989, only the Minister of Finance can grant such an Indemnity.

THEREFORE WITNESSES AS FOLLOWS:

1. Subject to clause 2, pursuant to section 65ZD of the Public Finance Act 1989, **I, THE HON DR MICHAEL CULLEN, MINISTER OF FINANCE** hereby give the Indemnity to Baxter Healthcare.

2. The Indemnity shall come into effect on the date the Agreement is executed.

EXECUTED as a Deed

SIGNED by the **HON DR MICHAEL CULLEN**)
MINISTER OF FINANCE in the presence of)

Witness:
Occupation: Senior Private Secretary
Address: Wellington

SCHEDULE

s 9(2)(b)(ii) & s 9(2)(ba)(ii)

DEED OF INDEMNITY

THIS DEED is made the 4th day of June 2009

BY **HER MAJESTY THE QUEEN** in right of New Zealand acting by and through the **MINISTER OF FINANCE** ("the Crown")

IN FAVOUR OF **BAXTER HEALTHCARE LIMITED**, having its registered office at 33 Vestey Drive, Mt Wellington, Auckland, New Zealand ("Baxter Healthcare")

BACKGROUND

A. The Crown acting by and through the Director-General of the Ministry Health is entering into an agreement for the supply of up to s 9(2)(b)(ii) doses of pandemic influenza vaccine ("the Contract");

B. Under clause 22 of the Contract, Baxter Healthcare requires that the Crown provide an indemnity in favour of Baxter Healthcare in the terms set out in the Schedule to this Deed; and

C. Under section 65ZD of the Public Finance Act 1989, only the Minister of Finance can grant such an indemnity.

THEREFORE WITNESSES AS FOLLOWS:

1. Subject to clause 2 of this deed, pursuant to section 65ZD of the Public Finance Act 1989, **I, THE HONORABLE SIMON WILLIAM ENGLISH AS MINISTER OF FINANCE** hereby indemnifies Baxter Healthcare on the terms set out in the Schedule to this Deed.

2. The indemnity shall come into effect on the date the Contract is executed by the Ministry of Health.

EXECUTED as a Deed

SIGNED by the **HONORABLE SIMON WILLIAM ENGLISH)**
MINISTER OF FINANCE in the presence of .)

Witness: GINA BUTSON
Occupation: SOLICITOR
Address: 34 MAJORIBANKS ST
MT VICTORIA
WELLINGTON

s 9(2)(b)(ii) & s 9(2)(ba)(ii)