### Hon Dr Megan Woods

MP for Wigram

Minister of Housing Minister of Energy and Resources Minister of Research, Science and Innovation



Associate Minister of Finance

31 August 2021

#### Scott

fyi-request-15933-1a03bc12@requests.fyi.org.nz

### **Dear Scott**

I refer to your email of 3 August 2021 requesting a copy of briefing "2021-2808 COVID-19 Vaccine Strategy: Investing in domestic production capabilities".

Please find the briefing attached in Annex 1. Please note that some information in the document has been withheld under the following sections of the Act:

6(a)	releasing the information would be likely to prejudice the security or defence of New Zealand or the international relations of the Government of New Zealand
6(b)(i)	releasing the information would be likely to prejudice the entrusting of information to the Government of New Zealand on a basis of confidence by the Government of any other country or any agency of such a Government
6(b)(ii)	information provided in confidence from an international organisation;
9(2)(a)	to protect the privacy of natural persons, including that of deceased natural persons
9(2)(ba)(i)	to protect information which is subject to an obligation of confidence, where the making available of the information would be likely to prejudice the supply of similar information, or information from the same source, and it is in the public interest that such information should continue to be supplied;
9(2)(f)(iv)	in order to maintain the confidentiality of advice tendered by Ministers of the Crown and officials;
18(d)	Withheld on the basis that the information requested is or will soon be publicly available

In terms of section 9(1) of the Act, I am satisfied that, in the circumstances, the decision to withhold information is not outweighed by other considerations that render it desirable to make the information available in the public interest.

I trust that you will find this information helpful; however, you have the right to seek an investigation and review by the Ombudsman of my decision on this request, in accordance with section 28(3) of the Act. The relevant details can be found at: <a href="https://www.ombudsman.parliament.nz">www.ombudsman.parliament.nz</a>.

Yours sincerely

Hon Dr Megan Woods

Minister of Research, Science and Innovation

Annex one: 2021-2808 - COVID-19 Vaccine Strategy - Investing in domestic

production capabilities



### **BRIEFING**

# COVID-19 Vaccine Strategy: Investing in domestic production capabilities

<b>Date:</b> 10 June 2021			Priority: Medium						
Security In Confidence classification:			Tracking number:	2021-2808					
Action sought									
		Action sough	Action sought		Deadline				
Hon Dr Megan Woods  Minister of Research, Science and Innovation  Agree that MBIE prepare advice 9(2)(f)(iv) to develop a domestic platform for RNA research and manufacturing									
Contact for telephone discussion (if required)									
Name	Position		Telephone		1st contact				
Simon Rae	Manager, In Science Par		O MINI						
Michael Contaldo	Principal Po Innovation F	licy Advisor, Policy	9(2)(a)		✓				
	·								
The following d	epartments/agenc	ies have beer	n consulted						
MFAT, Ministry of Health									
Minister's office t	o complete:	☐ Approved ☐ ☐ Noted ☐ ☐ Seen ☐ ☐ See Minister's Notes ☐		☐ Needs	<ul><li>□ Declined</li><li>□ Needs change</li><li>□ Overtaken by Events</li><li>□ Withdrawn</li></ul>				
Comments									



### **BRIEFING**

## COVID-19 Vaccine Strategy: Investing in domestic production capabilities

Date:	10 June 2021	Priority:	Medium
Security classification:	In Confidence	Tracking number:	2021-2808

Pι	ur	p	os	е

To seek your agreement for MBIE to prepare advice \$\frac{9(2)(f)(iv)}{2}\$ to develop a domestic platform for RNA research and manufacturing, in order to build domestic vaccine supply resilience and contribute to global vaccine manufacturing capacity.

### Recommended action

The Ministry of Business, Innovation and Employment recommends that you:

a Note that the COVID-19 Vaccine Strategy identified the need to investigate and develop New Zealand's domestic COVID-19 vaccine manufacturing capability, and allocated \$4.75 million to MBIE to support initial investments.

Noted

Note that MBIE has already invested \$2.88 million to upgrade BioCell's facilities, and has the potential to use the remainder of funds to support industry to build trial vaccine manufacture capabilities to complement the VAANZ platform.

Noted

Note that many countries are actively considering investing in domestic manufacture capabilities for vaccine production in order to be more resilient against continuing global supply chain uncertainty, including discussions being undertaken at the global level by the WHO, CEPI and the G7/G20.

Noted

d **Note** this creates an opportunity to consider whether, and how, New Zealand invests in domestic manufacturing capability to both improve our resilience and contribute to the regional and global supply of vaccines in the medium to long term

Noted

e 9(2)(f)(iv)

Simon Rae Manager, International Science Partnerships, MBIE 10 / 6 / 2021

Hon Dr Megan Woods

Minister for Research, Science & Innovation
..... / ...... / ......

### **Background**

### The COVID-19 Vaccine Strategy agreed to develop and invest in domestic vaccine manufacture capabilities

- 1. Under the COVID-19 Vaccine Strategy, MBIE led work to investigate and develop New Zealand's domestic COVID-19 vaccine manufacturing capability [CAB-20-MIN-0229 refers].
- 2. Cabinet allocated \$4.75 million to MBIE to support manufacturing, of which MBIE gave \$2.88 million to upgrade BioCell's facilities. The contract was signed in August 2020 and provides a five year option to use the facility if needed. It is expected that this should be ready by the second half of 2021.
- 3. Cabinet also allocated \$10 million for domestic COVID-19 vaccine research. MBIE funded the research platform Vaccine Alliance Aotearoa New Zealand (VAANZ) through the Malaghan Institute, and required it to connect with Biocell and South Pacific Sera to ensure links between research and manufacturing. The platform's contract with MBIE will conclude in 2021/22.

### New Zealand's COVID-19 vaccine purchasing meant short term manufacture was not necessary, but we have learnt lessons for future pandemic preparedness

- 4. Our success in securing timely vaccine purchase agreements for New Zealand has made domestic production unnecessary to cater for our needs in the immediate term. Despite this, our discussions with manufacturers during purchasing, and the global activity we have seen as COVID-19 vaccines have developed and rolled out, has taught us a number of lessons for future pandemic preparedness.
- 5. Vaccine development and production is an interconnected global system. Manufacture requires many inputs such that we consider it unrealistic for any country to be truly sovereign over manufacturing. Even the European Union, for example, was reliant on inputs from the United States in order to produce its COVID-19 vaccines. These supply chains are likely to remain strained, particularly in any future pandemic. There will be an ongoing risk of disruptions or delayed delivery for New Zealand (such as Italy's recent block of a shipment of AstraZeneca's vaccine to Australia, or India's continued block of vaccines to others including COVAX).
- 6. In order to meet the massive immediate demand for doses during a pandemic, production needs to scale up rapidly. This process takes time in the absence of prior preparedness. During COVID-19, manufacturers have had to scale up "as they go", which has slowed deliveries. One reason for this has been the lack of additional manufacturing facilities that can be easily be brought on stream, coupled with low numbers of technical experts who can ensure manufacturing is done to the required standard. The current proposal in the World Trade Organisation for a waiver around intellectual property is gaining traction, but many consider this will not unlock a production increase because technology transfer for vaccines remains complex and requires know-how that cannot easily be replicated or even codified.
- 7. The Coalition for Epidemic Preparedness Innovations (CEPI) predicts that in 2021 around 14 billion vaccine doses will be produced globally, while in 2019 the total number was only 3.5 billion (which includes seasonal flu shots). The sheer number of doses required to meet global demand is also putting pressure on supply chains for wider ingredients and materials (inputs and packaging such as plastic bags for bioreactors and glass vials).
- 8. Disease outbreaks will continue to occur, but their timing is unpredictable. The chances of a pandemic are relatively low, but the cost of being under-prepared is high, both to the economy and to wider society. At Alert Level 1, Treasury estimates that economic activity is 3 5% lower than normal. There is a risk that a future pathogen may be more lethal, and/or

harder to control, making it vital to apply learning on how to prevent and prepare for new pandemics.

#### A number of countries are building sovereign capacity to manufacture vaccines

- A number of larger and medium-sized countries are now turning their minds to how to improve their sovereign ability to produce vaccines, to create resilience against delays or active efforts by other countries to stop supplies moving across borders.
- 10. Australia has recently introduced a domestic manufacturing stimulus package which is aligned to a new work programme to reduce disruption risks to all supply chains. It includes government co-funding of AUS\$1 billion to partner with the local firm Segirus/CSL to build a biopharmaceutical manufacturing and storage plant with lab facilities. 6(a)
- 11. The UK is establishing a Vaccine Manufacturing and Innovation Centre to catalyse the growth of the domestic vaccine industry, and enhance domestic response capabilities to produce vaccines against emerging infections. Singapore and South Korea are also taking a pro-active approach, investing in new domestic vaccine manufacturing capacity and infrastructure. Canada is both investing in augmenting domestic vaccine manufacturing capability, including for new technology platforms such as messenger Ribonucleic Acid (mRNA). The EU has recently indicated it will support capacity building in parts of Africa to help better meet the needs of the continent going forward, and is supporting further scaling up of existing COVID-19 vaccine manufacturing plants for BioNTech's vaccine.
- 12. While these investments are being touted as boosting global capacity that can be drawn on for third country needs in any future pandemic, there is no guarantee this will be the case in practice, due to the pressure for countries to restrict vaccines exports until their own citizens are vaccinated. In many cases these investments may simply move the bottleneck further up the supply chain, to key inputs. There is also an emerging risk of a glut of global manufacturing capacity that eventually becomes unsustainable demand is unlikely to stay at the current level 14 billion doses of vaccines a year post-pandemic, and vaccine manufacturing capability needs to be in use continually in order to be sustained.

### There are calls for a more coordinated global network

- 13. Organisations such as CEPI and the WHO are beginning a global discussion on developing a network of more dispersed and proven manufacturing that can be used in times of emergency. This would differ from the current model where most production is concentrated in the EU or the US, or where countries try to cover the whole supply chain domestically.
- 14. MBIE recently met with officials from CEPI, including its Chief Executive Richard Hatchett. CEPI has recently launched its "2.0" Strategy which looks to widen its role in vaccine development beyond just R&D, and better help shape the global environment. CEPI's strategy is built around the ambitious goal of being able to develop and license a vaccine within 100 days in a pandemic. During COVID-19, CEPI has been central to the establishment of COVAX, and has acted as a facilitator between developers and manufacturers on issues such as technology transfer, adjuvant access, and the scale-up of manufacturing processes, and intends to expand this role under its next strategy.
- 15. [6(b)(ii) It envisages the establishment of a global network of "pre secured" manufacturing capability which could be drawn upon to ensure fast scale-up of the best candidate vaccines in a pandemic scenario but which would also operate sustainably between pandemics. There is also work underway between WHO and CEPI and industry to identify where bottlenecks and requirements for such as system are, and suggest improvements and required additional capacity to governments. However, CEPI

- has been clear that it does not by itself have the powers to direct this more integrated approach and would need governments to act.
- 16. CEPI indicated it could be attractive for a country the size of New Zealand to have some capacity contributing to this network as we could rapidly make enough doses in a crisis for our needs, then pivot to using the excess for export (in contrast to larger countries which have higher numbers of people and political pressure to vaccinate them first before export). They are willing to work with us to integrate any further steps we take into their approach.

### New Zealand could develop a research and industry platform around RNA technology

- 17. A credible and sustainable contribution to global vaccine manufacturing would need to:
  - Build on existing capabilities already present in New Zealand
  - Have wider technological application than just pandemic vaccines to be sustainable outside of a crisis period, and
  - Be integrated into global networks and developments to ensure access to technology and provide redundancy of supply
- 18. During the pandemic RNA has emerged as a vaccine technology that is both safe and effective in humans, and that has the advantage of rapid development and ease of manufacture. As a result there has been an explosion of commercial and research interest in RNA and its potential applications, which extend beyond human vaccines for infectious diseases to treatments for cancer, heart disease, also in animal health.
- 19. We have some key capabilities that could form part of a credible capability:
  - The Malaghan Insitute and Maurice Wilkins Institute have recognised expertise in immunology, as well as additional expertise on infectious diseases at Otago and Auckland Universities. This includes direct experience in the development of RNA therapeutics.
  - The Ferrier Institute at Victoria University has some existing expertise in RNA manufacturing, and lipid and carbohydrate chemistry, and there is additional manufacturing capability at Glycosyn and Callaghan Innovation
  - We have existing small scale biologics manufacturers in BioCell and SPS
  - We have some existing commercial and international relationships that could potentially be drawn into a wider platform
  - We have a body of potential demand for RNA technology that could sustain a platform, particularly once animal health applications are taken into account.
- We consider there is significant potential to work with the sector to develop a research and industry platform around RNA. This would involve creating a platform that would be able to provide a range of RNA services to human and animal health researchers. This would be underpinned by a body of capability, and bring together existing and some new hard infrastructure. Embedded in the platform would be the ability to manufacture RNA vaccines directly at either small scale or in a rapidly scalable format, and further investment in RNA technology development potentially aimed at goals such as simplifying technology transfer, improving vaccine stability, or developing new delivery systems (e.g. novel lipids).

### The Malaghan Institute has started drawing together a model but this needs to be verified

21. Professor Graham Le Gros, Director at Malaghan, has been actively looking to bring together donors to fund laboratory outlay and capital expenditure of around <sup>9(2)(ba)(i)</sup> to equip New

Zealand to conduct RNA vaccine development for clinical use. 9(2)(f)(iv)

22. We have not, as yet, conducted a proper assessment of the Malaghan proposal. It does appear to draw in the most critical capability within the New Zealand system, and Malaghan has sought to engage a wide range of stakeholders in its design. 9(2)(f)(iv)

### We will want to engage further with international partners

- 23. We are also looking to engage with international partners on vaccine development.

  Malaghan have told us they have already had interest in their plans from Australia, because it provides capabilities (notably readily available pilot scale manufacture) that Australian plans will not provide. Similarly we are unlikely to be able to match Australia's ambition to secure manufacturing facilities for vaccines produced by major multinationals, including CSL.

  6(b)(i) we have established a good working relationship with CEPI that we can continue to draw on.
- 24. We could potentially tag any investment as part of a further New Zealand contribution to the ACT-Accelerator, in response to a recent call made by the WHO, the EU and G20 for a second round of contributions. Having more manufacturing capability located in the Pacific region would be a valuable contribution to both CEPI and the ACT-Accelerator's vaccine equity and pandemic preparedness goals (CEPI is the lead agency for the vaccines pillar of the ACT-Accelerator).

### Relationship to VAANZ 18(d)

25. MBIE invested \$10 million to set up VAANZ to help screen, trial and accelerate potential domestic and international COVID-19 vaccines. However, the majority of the platform's research is only funded to October 2021 and we are concerned about whether the capability developed through the platform (for instance in vaccine candidate development and assessment) can be sustained long-term. Malaghan's intention is that their proposed RNA platform would pick up key parts of that capability and place it on a longer term funding path.

26. 18(d)

### **Next steps**

- **27**. 9(2)(f)(iv)
- 28. A next step would be to bring key partners around the table (including Malaghan) to understand more clearly the contribution each can make and how we can anchor the set of research, industry and international relationships through government engagement and investment.

## <u>Annex: Schematic showing potential relationship between research, industry and international collaboration</u>

