



BRIEFING

COVID-19 Vaccine Strategy – Early Progress

Date:	2 July 2020	Priority:	High
Security classification:	In Confidence	Tracking number:	MBIE: 3859 19-20

Action sought		
	Action sought	Deadline
Rt Hon Winston Peters Minister of Foreign Affairs	<p>Note early progress around action to deliver the Government's COVID-19 vaccine strategy</p> <p>Agree to forward this briefing to the Prime Minister, the Minister of Finance, and to the Minister for Trade and Export Growth</p>	9 July 2020
Hon Dr Megan Woods Minister of Research, Science and Innovation		
Hon Chris Hipkins Minister of Health		

Contact for telephone discussion (if required)			
Name	Position	Telephone	1st contact
Simon Rae	Manager, International Science Partnerships, MBIE	9(2)(a)	✓
Glenys Karran	Principal Adviser, MFAT	9(2)(a)	
Therese Egan	Principal Policy Analyst, Ministry of Health	9(2)(a)	

The following departments/agencies have been consulted
MFAT, Medsafe, PHARMAC, Treasury, MBIE, MoH

Minister's office to complete:

- | | |
|---|--|
| <input type="checkbox"/> Approved | <input type="checkbox"/> Declined |
| <input type="checkbox"/> Noted | <input type="checkbox"/> Needs change |
| <input type="checkbox"/> Seen | <input type="checkbox"/> Overtaken by Events |
| <input type="checkbox"/> See Minister's Notes | <input type="checkbox"/> Withdrawn |

Comments

BRIEFING

COVID-19 Vaccine Strategy – Early Progress

Date:	2 July 2020	Priority:	High
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Purpose

To provide an update on delivery of the COVID-19 Vaccine Strategy.

Recommended action

The Ministry of Business, Innovation and Employment, the Ministry of Foreign Affairs and Trade, and the Ministry of Health recommend that you:

- a **note** early progress around action to deliver the Government's COVID-19 vaccine strategy.

Noted

- b **note** good progress in implementing the COVID-19 vaccine strategy, directed by a task force and with advice from a Science and Technical Advisory Group.

Noted

- c **note** the rapidly changing international context, and that the task force is focused on:

- continuously updating information across all aspects of the developing science and global approaches.
- taking opportunities to share New Zealand knowledge and contribute to global developments
- planning in advance to harmonise and expedite regulatory processes
- exploring the full range of purchasing approaches
- planning for vaccine use in New Zealand in a range of scenarios
- contributing to global efforts towards equitable distribution

Noted

- d **note** that officials will provide further advice to joint Ministers on co-investment and/or advance purchase arrangements as these arise.

Noted

- e **note** that the task force is exploring opportunities for co-investment to scale up international manufacturing capacity and/or advance purchase arrangements

through a pooled facility and/or with groupings of countries, using its diplomatic networks.

Noted

- f **note** that MBIE has awarded \$2.88 million to the firm BioCell to develop a capability to manufacture COVID-19 vaccines as part of the contribution to expanding global vaccine supply.

Noted

- g **note** good progress in setting up and funding a COVID-19 vaccine research platform to rapidly build on domestic research capability.

Noted

- h **note** that a progress report will be provided to Cabinet during August, with recommendations on co-investment and/or advance purchase of vaccine, along with a communications strategy.

Noted

- i **Agree** to forward this briefing to the Prime Minister, the Minister of Finance, and to the Minister for Trade and Export Growth.

Agree / Disagree

9(2)(a)

Ben King
Deputy Chief Executive,
Ministry of Foreign Affairs & Trade

..... / /

Rt Hon Winston Peters
Minister of Foreign Affairs

..... / /

9(2)(a)

Maree Roberts
Deputy Director General
Ministry of Health

..... / /

Hon Chris Hipkins
Minister of Health

..... / /

9(2)(a)



Dr Peter Crabtree
**General Manager, Science,
Innovation, & International**
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..... / /

Hon Dr Megan Woods
**Minister of Research, Science and
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..... / /

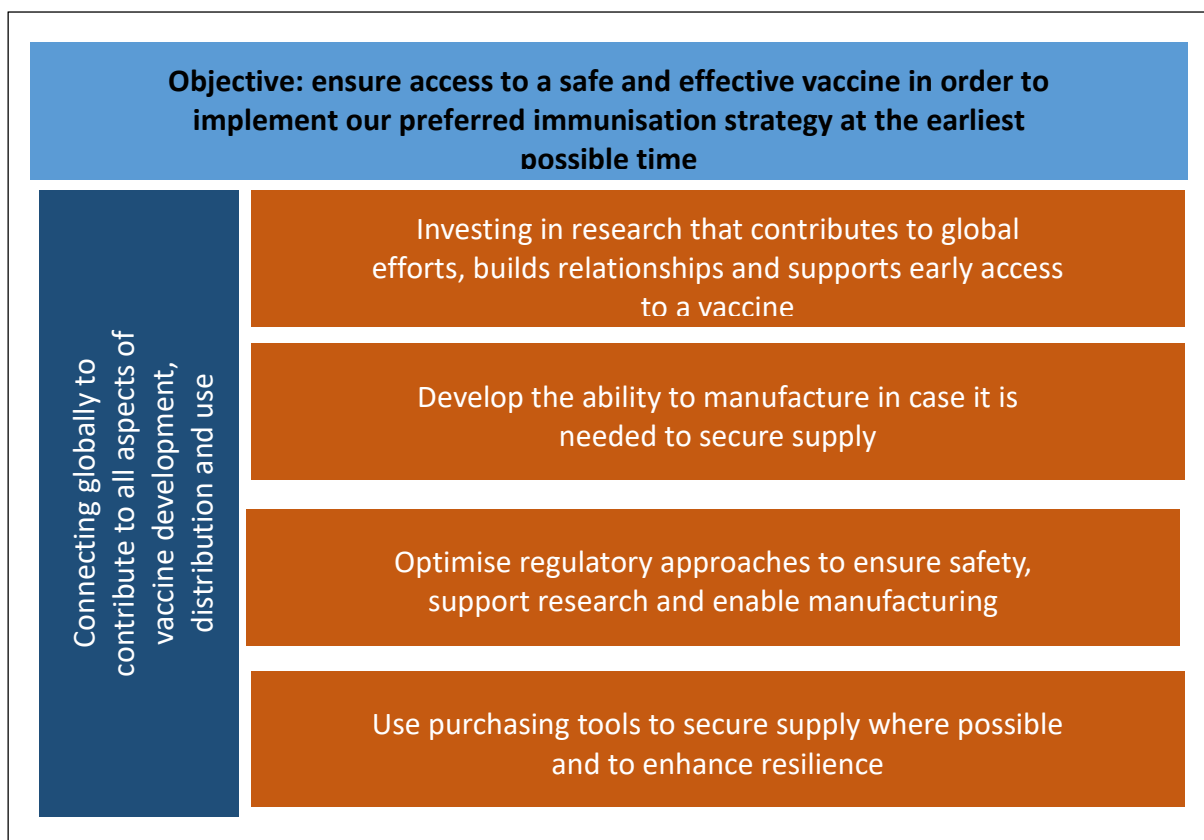
Executive summary

1. On 18 May Cabinet agreed a strategy [*Cab Min SWC-20-MIN-0042*] in order to secure adequate supply of a safe and effective vaccine against COVID-19 so we can fully re-open borders and progress with recovery. This strategy has been well received, a task force has been set up to oversee delivery and ensure pace is maintained, and work is well underway on a number of action areas.
2. The global context continues to rapidly evolve. Clinical trials are being conducted on a number of vaccine candidates, although some early contenders may only offer short-term immunity. We may need to consider the trade-offs between getting access to a vaccine quickly and its longer-term effectiveness.
3. 6(a) [redacted] Multilateral discussions are being led by Gavi, the Vaccine Alliance, which has launched a Vaccine Access Facility (COVAX) to speed-up vaccine production and share commercial risk. We have signalled our support in principle for a pooled approach, and are encouraging other countries to do the same. An alternative is to work with a smaller bloc of countries to aggregate demand, but we need to be careful this does not undermine a broader global approach if that attains critical mass. We are exploring both options in parallel.
4. New Zealand's \$37 million pledged contribution to support the work of the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi 6(a) [redacted] Engaging on defining "equitable access" is a current priority in international forums, because if we continue to remain COVID-free, countries with active outbreaks are likely to be seen as a more urgent priority.
5. The Ministry of Foreign Affairs and Trade (MFAT) has developed an International Engagement plan to engage its full diplomatic network, 6(a) [redacted]
6. The task force is developing a purchasing strategy with PHARMAC identifying which pharmaceutical companies are most likely to engage directly with us. Options such as securing an Advanced Purchasing Agreement (APA), obtaining licensing rights for local manufacture, or co-investment in manufacturing capacity off-shore, are all likely to require upfront investment by government.
7. Manufacturing capacity is a global issue, because producing enough doses of an effective vaccine will be an unprecedented challenge. New Zealand can play a role in contributing to wider supply by developing its own domestic capability. The Ministry of Business, Innovation and Employment (MBIE) has committed \$2.88 million to BioCell, a New Zealand based firm, to enhance capabilities so it can manufacture COVID-19 vaccines if they emerge.

8. MBIE has established a COVID-19 vaccine research platform, which will have a formal contract in place by mid-August. However, funding has already been provided so that research led by the Malaghan Institute of Medical Research and the University of Otago, already underway, can maintain its momentum.
9. The Ministry of Health (MoH) is developing an immunisation strategy with options for effective use of vaccine in a range of different circumstances. Key considerations include equity of outcomes, protection of those at high risk, ^{6(a)}
 [REDACTED]
 Medsafe is working with international colleagues to develop a shared framework to speed up efficacy and safety assessments for a vaccine where possible and therefore accelerate deployment.
10. A progress report will be provided to Cabinet during August, with recommendations on co-investment and/or advance purchase of vaccine, along with a communications strategy.

Background

11. On 18 May, Cabinet agreed a COVID-19 vaccine strategy to ensure access to a safe and effective vaccine. The strategy is built on five inter-related pillars (shown below):



Early progress towards delivery of the COVID-19 Vaccine Strategy

Key governance steps have been completed

12. A task force has been established to develop and implement a co-ordinated strategy at pace and to remove all roadblocks. This is chaired by Dr Peter Crabtree (MBIE), and includes Ministry of Health (MoH), MFAT, Treasury, PHARMAC, and Medsafe. It is being supported with expert advice from a Science and Technical Advisory Group which includes representatives from across the science and research community, chaired by Professor Ian Town (MoH).

The global context continues to evolve

13. The global context for the vaccine strategy continues to evolve. Vaccine research and development is a complex exercise. More than 150 individual research trials are currently underway; and production of human vaccines generally is dominated by a small number of global pharmaceutical firms.

14. To underline the critical importance of developing global connections, MFAT has developed an International Engagement plan for use across its diplomatic network, and intensified engagement with partners in Australia, Europe, Asia and the Americas to better understand priorities, and identify opportunities for collaboration. This plan identifies three high-level outcomes:

- a. *New Zealand makes a visible and valued contribution to global efforts.* Contributing to vaccine research, development, manufacture, regulatory processes and distribution ensures we play our part in helping accelerate development of a vaccine.
- b. *International conditions support early and equitable access for New Zealand and Pacific Island Countries.* To access a vaccine, we will need to influence norms – e.g. concerning equitable access to vaccines – and ensure fair trade and regulatory rules, as well as advocate for collaborative approaches that recognise the global need for health and economic security.
- c. *New Zealand supports regional immunisation efforts, especially in Pacific Island Countries.* ^{6(a)}

15. Purchasing from an overseas manufacturer is emerging as the quickest and most likely route to securing a safe and effective vaccine for use in New Zealand. This might be done either directly, as part of a bloc of countries, or through a global pooled facility.

16. On 29 May, New Zealand pledged \$37 million to the WHO-led Access to COVID-19 Tools (ACT) Accelerator, including a contribution to Gavi. This was well received, ^{6(a)}

[REDACTED], as well as helping accelerate the pace of vaccine development more generally. Officials continue to engage on the definition of “equitable access” in this context, as the absence of domestic transmission in New Zealand and some Pacific island countries is likely to mean that other countries are seen as higher priority in terms of first access under a global allocation formula.

17. On 4 June, Gavi launched plans for a Global COVID-19 Vaccine Access Facility (COVAX) as a pooled purchasing initiative to accelerate access to vaccines by spreading risk across a number of potential vaccine makers. It has a fundraising goal of US\$2 billion. Any country is welcome to participate by providing a financial contribution in advance, and committing to buy vaccine doses once developed. New Zealand needs to consider buying into such an initiative because by pooling funds with others we will be able to spread our risk over a larger portfolio of vaccine candidates. In separate advice, we are recommending to the Minister of Foreign Affairs that New Zealand expresses interest in participating in the COVAX Facility. ^{6(a)} [REDACTED]

[REDACTED] Officials will work with Gavi and other participating countries to shape the COVAX Facility and will report back to Cabinet on options in August.

18. We have also seen efforts to aggregate demand to negotiate advance purchase agreements between suppliers and smaller groupings of countries, and officials are also exploring options to partner with other countries where there is likely to be strongest interest in collaboration.

19. As an immediate priority, our High Commissioner to Australia, Dame Annette King, has signalled the importance New Zealand places on working with Australia, and there seems to be strong appetite for an “ANZAC” approach. Officials have also held initial conversations with Pacific Island governments in partnership with Australia on their interests.

20. ^{6(a)} [REDACTED]

Purchasing strategy

Purchasing strategy options are being explored and kept open

21. The task force has set up a working group chaired by PHARMAC and with the participation of MoH and other agencies to urgently develop a vaccine purchasing strategy, with the aim of informing the international engagement plan, and maintaining strong inter-connection with the emerging immunisation strategy.
22. PHARMAC has good working relationships with a wide range of pharmaceutical companies who supply vaccines to New Zealand. Normally, where global vaccine availability is constrained, supply is prioritised in sequence to countries with the most serious disease outbreaks, then contracts for government immunisation

programmes, and finally private market supply. However, the COVID-19 pandemic is not typical, and we need to consider the balance of interest for New Zealand between control of COVID-19 outside our borders, given that our border poses the greatest risk of the disease re-emerging in the country, and our wider domestic needs.

23. The working group is currently collecting information on the suppliers most likely to emerge, to determine which pharmaceutical firms we will need to try to engage with if we approach this outside of a pooled initiative, and ideally through securing an advanced purchasing agreement which would reduce some commercial risk for the firm, and help ensure we have a committed provider in place.
24. The task force has also commissioned the task force's Science and Technical Advisory Group to review available information on the effectiveness of promising international vaccine candidates to help inform the purchasing plan and identify priorities for engagement.

Manufacturing approach

Our approach to manufacturing is placing greater emphasis on supporting global supply

25. A number of countries and pharmaceutical companies are actively thinking about how they might scale-up and invest in manufacturing capacity now to accelerate immunisation. We have likewise already mapped domestic manufacturing capabilities.
26. Demonstrating experience, or a convincing potential capability in producing vaccines to very high standards, is critical in building relationships with the larger pharmaceutical firms that would need to transfer licensing rights to manufacture a potential vaccine here. However, New Zealand's current vaccine manufacturing capability presents both challenges and opportunities.
27. We do not have a track record in producing vaccines for human use, but two firms, South Pacific Sera (SPS) and BioCell, do have experience contract manufacturing animal vaccines for demanding European or North American markets. Both operate facilities that have a degree of flexibility that may allow them to be reconfigured for human vaccine production. At the same time, we also have two human medicines manufacture firms, Baxter Healthcare and Douglas Pharmaceuticals, which have expressed an interest in how they might support domestic vaccine production more generally.

MBIE will invest initially in scaling up manufacturing capability in one firm

28. Conversations with BioCell have progressed more rapidly than with others, and MBIE has committed \$2.88 million to help develop a commercially meaningful contract manufacturing capability for a fraction of the normal cost to potentially produce COVID-19 vaccines. It has confirmed that it has the associated technologies, equipment, utilities, and scientific and technical skillset to develop most of the main vaccine candidates under consideration. MBIE is negotiating the

terms of the funding agreement with BioCell, with the aim of securing an option to manufacture COVID-19 vaccines for a period of five years.

29. 9(2)(g)(i), 9(2)(ba)(i)

However, there are significant political and security of supply opportunities for New Zealand in supporting BioCell's engagement with international discussions and pharmaceutical firms seeking additional contract manufacturing capacity, and we will be looking at how we can integrate BioCell's capability into our wider international engagement.

30. This would leave \$1.87 million remaining from the \$4.75 million originally allocated to support manufacturing capacity, and leaves open the opportunity of supporting a complementary capability with another partner on the same basis if an opportunity arises. For example, we know SPS is considering a more ambitious proposal to provide New Zealand with a long-term strategic capability to manufacture vaccines. However, a facility of this nature would rely on a policy justification broader than the current pandemic, and would need to draw in a broader range of partners. We understand SPS is considering a bid into the Provincial Growth Fund for support.

31. Medsafe has also re-prioritised resource to speed up assessment for any New Zealand firm looking to build manufacturing capability for a COVID-19 vaccine, including adherence to Good Manufacturing Practice.

32. 6(a)

Customised regulatory approaches are being agreed in advance

33. Medsafe is working with regulatory colleagues internationally, maintaining line of sight on clinical trials around the world and helping develop an international framework for regulating COVID-19 vaccines which may speed up ultimate deployment, particularly where vaccines use novel technologies. This framework is organised around the five main vaccine technology platforms, each of which will have different assurance and monitoring arrangements.

Update on research platform

We have made substantial progress with the setting up of the research platform

34. Good progress has been made in setting up a COVID-19 vaccine research platform, which will develop domestic capacity to contribute to wider global efforts. At the same time, it will help build our capabilities in the development, production and supply of other human vaccines. New Zealand researchers will provide valuable intelligence on vaccine developments around the world which will be critical to informing our purchasing strategy and individual decisions.

35. Total funding available is \$10 million. Funding of \$0.83 million has already been provided to support critical research. MBIE is working with the Malaghan Institute of Medical Research and the University of Otago on the design of the platform, so that a contract can be finalised by mid-August and ensure we meet the expectations of the overall strategy, to conduct high-quality scientific research, and make a credible contribution to wider international research. An expert panel, including representatives from the Advisory Group are helping to assess the plan, and officials are also engaging with CEPI on the proposed approach.
36. Officials have also given consideration to the potential to host clinical trials for COVID-19 vaccine candidates. The most likely contribution New Zealand could make would be as part of a larger international study whereby our COVID-19 free status and population characteristics would be of particular value – for instance to provide a control group, or to test antibody responses in the absence of exposure. Both Medsafe and the Health and Disability Ethics Committees have agreed to prioritise assessments for clinical trials related to COVID-19 for completion within five days of receiving an application.

Immunisation strategy

Immunisation strategy scenarios and an economic model are being built

37. MoH is developing an immunisation strategy. Though of much greater scale, it will benefit from experience gained in the successful HPV and Meningococcal B immunisation programmes, the MMR immunisation campaign plans currently being finalised by DHBs, and earlier pandemic influenza planning.
38. Decisions on the objectives and priorities for using a vaccine will be dependent on many unknowns, including:
 - a. *the situation* (do we have current disease or outbreaks, quantity of vaccine, greatest transmission sources);
 - b. *the disease* (who is at risk of getting it, passing it on, becoming severely ill);
 - c. *the vaccine* (who is it effective for, safe for, how long does protection last, are there vaccine choices, what delivery mechanisms are used);
 - d. *alternatives* (other means of prevention, treatment or mitigation).
39. Research results from early phase 1 suggest that at least some early vaccines will produce only limited immunity. Any vaccine is expected to be in high demand and short supply at least initially. There are therefore likely to be significant trade-offs required when deciding on how best to use any vaccine that might be available to us.
40. Choices may be dependent on whether we have sufficient vaccine to immunise our population, or whether we will need to protect those most at risk of getting and transmitting the disease (such as airport or hotel workers), or of severe illness (such as people with pre-existing health conditions, or advanced age), or

possibly of both (such as frontline health workers). We will also want to think about those entering or leaving at the border, and which is critically tied to the ability of the country to open up socially and economically and progress with the recovery.

41. Officials are starting to build scenarios which will explore what effective use and equitable distribution of a COVID-19 vaccine would involve in a wide range of situations. Work on these scenarios is contributing to the developing WHO global allocation framework, and helping prepare for future decisions and risk management for vaccine choice and use within New Zealand. Alongside the scenarios, an economic model is being developed to help weigh up the many factors and likely trade-offs involved in decisions about vaccine purchase and use.
42. These difficult choices may continue for some time if initial research produces vaccines that are partially effective or in limited supply.
43. MoH is convening an Immunisation Advisory Group during July to advise on development of the immunisation strategy. The Group, along with the Science and Technical Advisory Group and Te Ropu Whakakaupapa Urutā (the National Māori pandemic Group), will help guide the strategic approach to use of a vaccine as well as potential vaccine choices, purchasing approaches and decisions.

Financial implications

44. There are no financial implications arising as a result of this briefing. However, we expect the August report to Cabinet to give a clearer sense of what funding would be needed to secure entry into and participate in a multi-lateral purchasing mechanism such as the COVAX Facility, or other pooled initiatives, and/or to finance advanced purchase agreements outside of these.

Communications

45. We do recognise communications as a critical part over coming months and so a more fulsome communications strategy will form part of the report to Cabinet in August.

Recommendations

Officials from the Ministry of Business, Innovation and Employment, the Ministry of Foreign Affairs and Trade, and the Ministry of Health recommend that Ministers:

- 1 **note** good progress in implementing the COVID-19 vaccine strategy, directed by a task force and with advice from a Science and Technical Advisory Group.
- 2 **note** the rapidly changing international context, and that the task force is focused on:
 - 2.1 continuously updating information across all aspects of the developing science and global approaches.

- 2.2 taking opportunities to share New Zealand knowledge and contribute to global developments
- 2.3 planning in advance to harmonise and expedite regulatory processes
- 2.4 exploring the full range of purchasing approaches
- 2.5 planning for vaccine use in New Zealand in a range of scenarios
- 2.6 contributing to global efforts towards equitable distribution
- 3 **note** that officials will provide further advice to joint Ministers on co-investment and/or advance purchase arrangements as these arise.
- 4 **note** that the task force is exploring opportunities for co-investment to scale up international manufacturing capacity and/or advance purchase arrangements through a pooled facility and/or with groupings of countries, using its diplomatic networks.
- 5 **note** that MBIE has awarded \$2.88 million to the firm BioCell to develop a capability to manufacture COVID-19 vaccines as part of the contribution to expanding global vaccine supply.
- 6 **note** good progress in setting up and funding a COVID-19 vaccine research platform to rapidly build on domestic research capability.
- 7 **note** that a progress report will be provided to Cabinet in August, with any recommendations on co-investment and/or advance purchase of vaccine, along with a communications strategy.
- 8 **Agree** to forward this briefing to the Prime Minister, the Minister of Finance, and to the Minister for Trade and Export Growth.