SWC-20-MIN-0098

Cabinet Social Wellbeing Committee

Minute of Decision

COVID-19 Vaccine Strategy: Early Progress

Portfolios **Foreign Affairs / Research, Science and Innovation / Health**

On 22 July 2020, the Cabinet Social Wellbeing Committee:

1 **noted** that good progress has been made in implementing the COVID-19 vaccine strategy, directed by a task force and with advice from a Science and Technical Advisory Group;

2 **noted** that the international context is rapidly changing, 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 **noted** 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;

4 **noted** that the Ministry of Business, Innovation and Employment 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;

5 **noted** that good progress is being made in setting up and funding a COVID-19 vaccine research platform to rapidly build on domestic research capability;

6 **noted** that the Minister of Foreign Affairs, Minister of Research, Science and Innovation, and the Minister of Health will provide a Cabinet paper in August 2020 that will seek agreement to a contingency fund to support investment in advance purchase and production of COVID-19 vaccine and preparation for its use.

Charlotte Doyle
Committee Secretary

Present:
Rt Hon Winston Peters
Hon Kelvin Davis
Hon Grant Robertson
Hon Dr Megan Woods
Hon Chris Hipkins
Hon Andrew Little
Hon Carmel Sepuloni (Chair)
Hon David Parker
Hon Nanaia Mahuta
Hon Stuart Nash
Hon Jenny Salesa
Hon Damien O'Connor
Hon Tracey Martin
Hon Aupito William Sio
Hon Julie Anne Genter
Jan Logie, MP

Officials present from:
Office of the Prime Minister
Officials Committee for SWC
Office of the SWC Chair

[In Confidence]

Office of the Minister of Foreign Affairs

Office of the Minister of Research, Science and Innovation

Office of the Minister of Health

Chair, Cabinet Social Wellbeing Committee

COVID-19 Vaccine Strategy – early progress

Proposal

1 This paper provides an update on early progress to deliver the Government's COVID-19 Vaccine Strategy.

Executive Summary

2 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 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.

3 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.

4 6(a) 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. 6(a)

5 New Zealand's $37 million pledged contribution to support the work of the Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi, 6(a) 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.

6 The Ministry of Foreign Affairs and Trade (MFAT) has developed an International Engagement Plan to engage its full diplomatic network, 6(a) [redacted]

7 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 advance purchase arrangements, obtaining licensing rights for local manufacture, or co-investment in manufacturing capacity off-shore, are all likely to require upfront investment by government.

8 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 the majority of potential COVID-19 vaccine platforms if they emerge.

9 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.

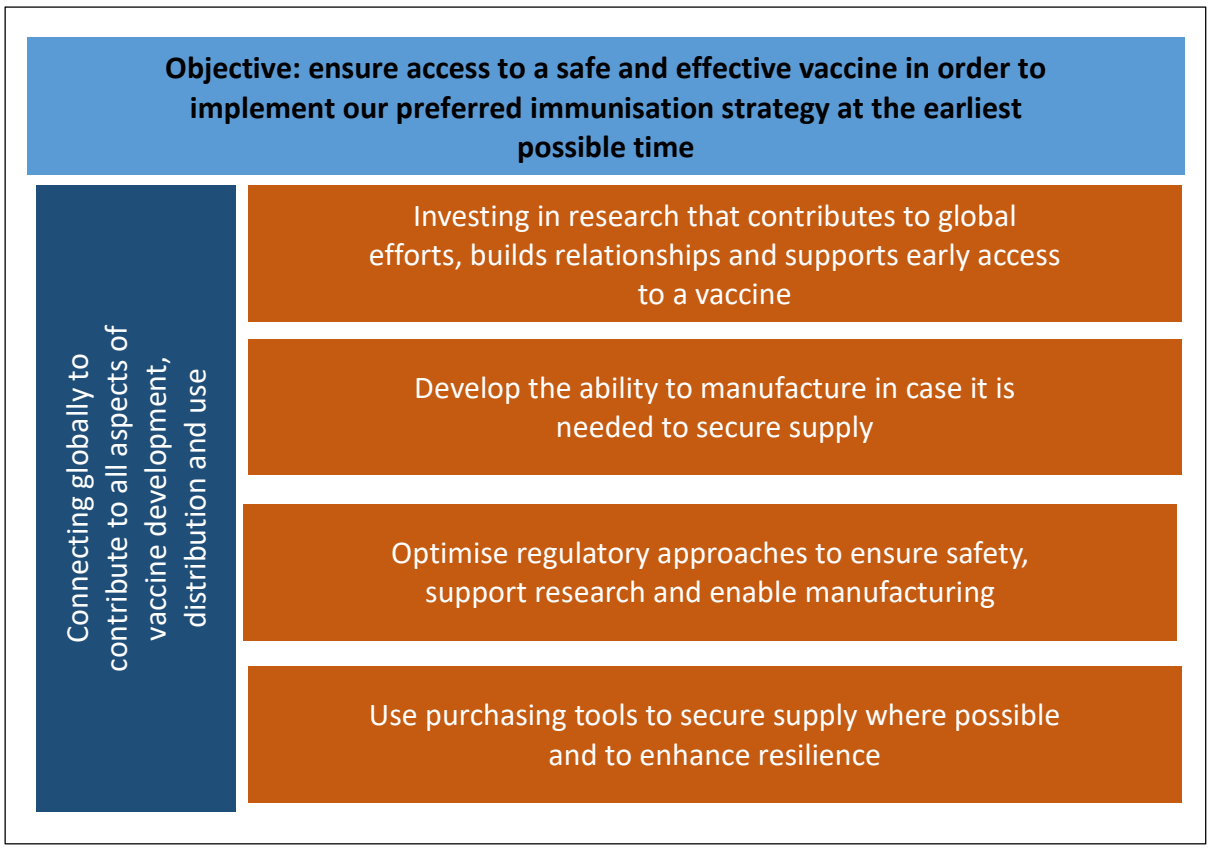
10 The Ministry of Health (MoH) is developing an immunisation strategy with options for effective use of a vaccine in a range of different circumstances. Key considerations include equity of outcomes, protection of those at high risk, 6(a) [redacted] Medsafe is working with international colleagues to develop a shared framework to speed up efficacy and safety assessments for a vaccine where possible and therefore accelerate deployment.

11 We will provide a separate Cabinet paper in August that will seek agreement to a contingency fund to support investment in advance purchase and production of COVID-19 vaccine and preparation for its use.

Background

12 On 18 May, Cabinet agreed a COVID-19 vaccine strategy to ensure access to a safe and effective vaccine. Ministers were invited to report back in June 2020, and then at least quarterly.

13 The strategy is built on five inter-related pillars (shown on the next page):



Key governance steps have been completed

14 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 MBIE, 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

15 The global context for the vaccine strategy continues to evolve. Vaccine research and development is a complex exercise. More than 170 individual research trials are currently underway; and production of human vaccines is generally dominated by a small number of global pharmaceutical firms.

16 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) [redacted]

17 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.

18 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. On 30 June, New Zealand formally expressed interest in participating in the COVAX Facility, and we understand a total of 70 self-financing countries have also expressed interest. Officials will work with Gavi and other participating countries to shape the COVAX Facility and will report back to Cabinet on options in August.

19 The COVAX Facility is following the WHO global allocation framework. This framework seeks to ensure all countries have access to vaccines for 20% of their populations first, before any countries access more than that. WHO envisages that 20% populations coverage would provide immunisation for frontline health workers and other groups at high risk (eg, over 65 year olds).

20 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 the strongest interest in collaboration.

21 Conversations with Australia are well underway at a range of levels. 6 [redacted]

6(a) Officials have also held initial conversations with Pacific Island governments in partnership with Australia on their interests.

22 6(a)

Purchasing strategy options are being explored and kept open

23 Purchasing vaccine produced overseas, rather than in New Zealand will probably be 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.

24 The task force has set up a purchasing working group, chaired by PHARMAC, which has developed a draft purchasing strategy with the aim of informing the International Engagement Plan, and maintaining strong inter-connection with the emerging immunisation strategy.

25 PHARMAC has good working relationships with a wide range of pharmaceutical companies who supply vaccines to New Zealand and is working with MFAT to identify any new relationships that need to be developed. 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.

26 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. This would likely be 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.

27 In addition, PHARMAC has recently issued a Request for Information (RFI) seeking information from firms on COVID-19 vaccine research, manufacture and supply, including supplier willingness to consider a range of different commercial scenarios for supply to New Zealand. PHARMAC is also working with MFAT to directly reach out to start conversations with major international pharmaceutical companies.

28 The task force has also commissioned the 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.

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

29 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.

30 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.

31 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 medicine manufacturing 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

32 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.

33 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.

34 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.

35 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, this involves assessment in relation to Good Manufacturing Practice regulatory requirements.

36 6(a) [redacted]

Customised regulatory approaches are being agreed in advance

37 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.

We have made substantial progress with setting up the research platform

38 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.

39 The total funding available for the programme is $10 million and 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 to make a credible contribution to wider international research. An expert panel, including representatives from the Advisory Group are helping to assess the plan.

40 We have also engaged with CEPI on the platform's proposed research. CEPI is positive about the proposed research approach and has offered New Zealand access to its expertise.

41 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 scenarios and an economic model are being built

42 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.

43 Also key to a successful mass-scale COVID-19 immunisation programme will be the new immunisation data and digital solution being built to replace the outdated immunisation register. The new solution will be operational to support a COVID-19 programme by early 2021, and enhanced user interfaces (such as a provider front-end for multiple delivery modes from malls to drive-throughs, or app for personal record and reminders) will be added in the first half of 2021.

44 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).

45 Research results from early phase 1 clinical trials 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.

46 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 advance immunisation for those entering or leaving at the border if this supports country bubble expansion to other low-risk countries (such as in the Pacific) or travel of high importance to New Zealand.

47 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.

48 These difficult choices may continue for some time if initial research produces vaccines that are partially effective or in limited supply.

49 MoH is convening an Immunisation Advisory Group in 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

50 There are no financial implications arising as a result of this paper. However, we will be seeking a funding envelope to support advanced purchasing arrangements for COVID-19 vaccines, including funding to participate in the COVAX Facility, in our next Cabinet paper in August.

Legislative Implications

51 There are no legislative implications arising from this Cabinet paper.

Population Implications

52 There are no population implications arising from this Cabinet paper. Failure to achieve the objectives of this strategy would be likely to delay full cultural, social and economic recovery from COVID-19, with flow-on implications for particular population groups. Māori, Pacific peoples, disabled people and young people are likely to see greater impacts from lower employment and reduced activity in export and tourism industries. People with family outside New Zealand would continue to be impacted by border closure.

Consultation

53 The Treasury, Medsafe, and PHARMAC have been consulted in the preparation of this Cabinet paper. The Department of Prime Minister and Cabinet has been informed.

Communications

54 We do not propose any communications or announcements as a result of this Cabinet paper.

55 We do however recognise communications as playing a critical part over coming months and will provide an update on a more fulsome communications strategy in our August paper.

Proactive Release

56 We intend to release this Cabinet paper in accordance with the agreed approach to proactive release. Parts of the Cabinet paper will need to be redacted to protect our commercial and foreign policy interests.

Recommendations

The Minister of Foreign Affairs, Minister for Research, Science and Innovation, and the Minister of Health recommend that the Committee:

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

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

6 **note** that the Minister of Foreign Affairs, Minister of Research, Science and Innovation and the Minister of Health will provide a Cabinet paper in August that will seek agreement to a contingency fund to support investment in advance purchase and production of COVID-19 vaccine and preparation for its use.

Authorised for lodgement

Rt Hon Winston Peters

Minister of Foreign Affairs

Hon Dr Megan Woods

Minister for Research, Science and Innovation

Hon Chris Hipkins

Minister of Health