

~~Commercially Sensitive~~

Office of the Minister for COVID-19 Response

Cabinet

Decision to proceed with a booster programme for the COVID-19 Vaccine and Immunisation Programme

Proposal

- 1 The paper seeks your agreement to proceed with a booster programme for the COVID-19 Vaccine and Immunisation Programme.

Executive Summary

- 2 Medsafe have approved the use of the Pfizer COVID-19 vaccine as a booster dose (third dose) for people 18 years of age or over with a minimum six-month interval between their second and third dose.
- 3 It is now around 8 months since the first doses of the Pfizer vaccine were administered in New Zealand and a decision is required on proceeding with a booster programme.
- 4 Current evidence shows that immunity produced by the Pfizer vaccine wanes over time, particularly from 6 months after a primary vaccination course. Providing a booster dose has been shown to achieve a relative vaccine efficacy of 95.6 percent efficacy against symptomatic (predominantly Delta-variant) disease in a randomised trial, when compared to two primary doses. This represents a restoration of the protection provided by the original two-dose course.
- 5 The COVID-19 Vaccine Technical Advisory Group (CV TAG) have provided their recommendations, following regulatory approval by Medsafe, noting that:
 - 5.1 increasing the vaccination coverage of first and second doses, particularly for Māori and Pacific, should remain the first priority of our COVID-19 Vaccine and Immunisation Programme (CVIP); and
 - 5.2 offering booster doses will reduce the risk of severe disease caused by COVID-19, reduce burden on hospitals and other healthcare providers, and protect those at high occupational risk of exposure.
- 6 I am seeking your agreement to proceed with a booster programme from 29 November 2021. Given the requirement for a six-month interval this will mean that people are eligible primarily based on the rollout in 2021. To address the recommendations from CV TAG the CVIP will look to ensure that we achieve high uptake and coverage across at-risk groups as they become eligible.

- 7 There is sufficient supply of the Pfizer vaccine in the remainder of 2021 and into 2022. To achieve our preferred implementation timeline, delivery schedules will need to be adjusted to provide sufficient supply in Q1 and Q2 of 2022. Officials have prepared advice for Vaccine Ministers on how this will be managed.
- 8 In line with our close relationships and people-to-people ties in the Pacific, Cabinet agreed that New Zealand will provide ongoing support for the Realm and that officials will work with other donors to ensure that the ongoing immunisation needs of Tonga, Samoa, Tuvalu and Fiji are met [CAB-21-MIN-0350 refers].
- 9 I am now seeking your agreement to proceed with donation of boosters to the Realm in line with New Zealand's immunisation programme and for officials to explore, in coordination with other donors, opportunities to support Samoa, Tonga, Tuvalu and Fiji to access boosters, and consider donating supply from our domestic portfolio if requested, subject to supply availability and appropriate regulatory approvals.

Context

The COVID-19 Vaccine Immunisation Programme is making progress toward reaching the goal of 90% coverage across DHB regions

- 10 The context in which New Zealand is executing its COVID-19 Vaccine Immunisation Programme (CVIP) is evolving, accounting for increasing community cases, increasing vaccination rates, and shifting public health settings.
- 11 As of 10 November, 79 percent of the eligible population are fully vaccinated and 89 percent had received their first dose.

There is a continued focus on achieving high vaccination rates and equitable coverage across New Zealand

- 12 Uptake of an initial vaccine course continues to be the key focus of the Immunisation Programme given the strong evidence that vaccines provide a level of personal protection and are effective at reducing the risk of severe outcomes from COVID-19, including COVID-19 associated hospitalisation and death.
- 13 As of 3 November, over 72 percent of COVID-19 community cases and 93 percent of those requiring hospitalisation were not fully vaccinated or unvaccinated, in comparison to 7 percent of community cases and 2 percent of hospitalisations who were fully vaccinated.
- 14 To support our efforts in reaching those who are unable or hesitant to take the Pfizer vaccine, Cabinet approved the use of the AstraZeneca COVID-19 vaccine [CAB-21-MIN-0460]. People who wish to receive the AstraZeneca vaccine will be able to make a booking for this from 25 November 2021.

I am now seeking your agreement to proceed with a booster for the CVIP

- 15 On 8 November 2021, Medsafe granted the Pfizer vaccine provisional approval for use in booster immunisations.

- 16 It is now approximately 8 months since the first doses of COVID-19 vaccine were administered in New Zealand. Given that Medsafe have now approved the Pfizer COVID-19 vaccine for use with a minimum 6-month interval following the primary course a decision is required on whether and when to proceed with a booster programme.
- 17 I am seeking your agreement to proceed with a booster programme. This has been considered against the Decision to Use Framework, taking account of the context that New Zealand is in and the advice provided by the COVID-19 Vaccine Technical Advisory Group (CV TAG) and the Ministry of Health. It also considers available supply of vaccine, the implementation approach and timing and our role in supporting international efforts and our Pacific neighbours.

Use of a booster COVID-19 vaccine

Why are boosters required?

- 18 There are three main reasons for offering an additional dose following a two-dose primary course of a COVID-19 vaccine:
- 18.1 to increase protection in immunocompromised individuals;
 - 18.2 to protect against variants; and
 - 18.3 to extend the duration of protection in the wider population, particularly if immunity is waning.
- 19 Immunocompromised people are currently being offered a third dose of the Pfizer vaccine as part of their primary course. They are offered a third primary dose because they have a weakened immune system, meaning they may have an impaired immune response. This may prevent the vaccines from being able to generate a sufficient protective effect, and immunocompromised people are left at high risk of severe outcomes from disease even after vaccination. CV TAG has previously provided specific advice around this third dose in the immunocompromised, and has now provided recommendations around booster doses (fourth dose) in this group.
- 20 An additional dose may also provide enhanced protection against variants by simply increasing the overall existing immune response. Alternatively, if and when variant-specific vaccines become available then they would target the new variant. Officials are continuing to negotiate with suppliers to ensure, where possible, that we can access updated or new vaccines that may provide better protection against variants.

There is emerging evidence of waning immunity

- 21 The duration of immunity varies with different diseases and different vaccines, this will also be the case for the Pfizer vaccine and COVID-19.¹ Booster vaccinations are

¹ Lifelong protection is not always provided by either natural infection (getting the disease) or vaccination. The recommended timing of vaccine doses aims to achieve the best immune protection to cover the period in life when vulnerability to the disease is highest. The duration of immunity provided by vaccines varies depending on a range of factors, particularly the vaccine itself. For example, protection from the measles vaccine is life-long in almost all individuals (>96% of individuals); however, for pertussis (whooping cough) the duration of protection is 4-6 years. Furthermore, the influenza vaccine is a seasonal vaccine that is updated annually to offer protection against new forms of virus.

required throughout life for some vaccine (eg, tetanus) to maintain vaccine-induced immunity.

- 22 Current evidence shows that immunity produced by the Pfizer vaccine wanes over time following the second dose, and that there is a reduction in protection against infection, particularly from 6 months after a primary vaccination course. Early data suggests that this is more prominent in older people who are more at risk of severe disease and death from COVID-19. The reduction in protection is similar for Delta and other virus variants. Protection against onward transmission by vaccinated people also appears to wane over time.
- 23 However, there is evidence that protection against severe disease remains high over time, including for the Delta variant. The evidence both in New Zealand and overseas continues to reiterate that there is a stark difference between vaccinated and unvaccinated individuals, particularly for those who are most at risk of COVID-19.

Internationally there are already a number of countries recommending and offering boosters

- 24 Internationally, a number of regulatory and advising bodies including the United States Centres for Disease Control and Prevention, the United Kingdom's Joint Committee on Vaccination and Immunisation, and the Australian Technical Advisory Group on Immunisation, have recommended booster doses for high-risk individuals, no less than 6 months after their initial course.

Evidence of effectiveness

- 25 On 21 October 2021, Pfizer released preliminary trial data indicating that boosters of the Pfizer vaccine achieved 95.6 percent relative efficacy against symptomatic disease (compared to two primary doses and no booster dose) during period in which Delta was the prevalent strain of transmission. This represents a restoration of the protection provided by the original two-dose course.
- 26 An additional dose is expected to increase protection against infection and disease, particularly in older people where waning appears more marked. Data from Israel, where booster doses have been administered to large numbers of people, show reductions in all eligible age groups in the rate of infection, as well as severe disease in those aged 40 years and over, and deaths in those 60 years and over, after the booster dose.
- 27 There isn't evidence available at this time on whether following a booster dose protection against infection and disease wanes and officials and CV TAG will continue to review information as it becomes available.

CV TAG Recommendations

- 28 CV TAG met on 2 and 9 November 2021 to consider recommendations regarding priority groups for COVID-19 booster vaccinations. Their recommendations and advice have been provided to the Director-General of Health.
- 29 It was noted that the goal of offering booster doses in New Zealand is to prevent severe disease caused by SARS-CoV-2, to reduce burden on hospitals and other healthcare providers, and to protect those at high occupational risk of exposure.

- 30 Data are still accumulating on waning immunity following primary vaccination and the benefits of a booster dose and there is limited data for some population groups, including people younger than 30 years of age and pregnant people and this has been considered against the risks posed by COVID-19.
- 31 CV TAG have also noted that Māori and Pacific people are at an increased risk of severe disease and hospitalisation, and therefore having a universal age-criteria for prioritisation is inequitable.
- 32 Increasing the vaccination coverage of first and second doses, particularly for Māori and Pacific, should remain the first priority of the COVID-19 vaccination programme in New Zealand.
- 33 CV TAG recommended that:
- 33.1 the Pfizer vaccine is recommended as a single booster dose;
 - 33.2 COVID-19 vaccine booster doses should be offered to those 18 years of age and older, who have completed their full primary vaccination course 6 or more months prior;
 - 33.3 those aged over 18 who are immunocompromised and have received a third primary dose of a COVID-19 vaccine as described in previous CV TAG recommendations, should only receive a booster dose 6 months after completion of their primary course (i.e., 6 months after their third dose);
 - 33.4 any future vaccine mandates should not require booster doses in younger age groups (<30 years) until further data is available;
 - 33.5 when considering prioritisation, priority groups for a booster dose (at least 6 months after completion of the primary course) are those most at risk of exposure to SARS-CoV-2, and those most at risk from serious COVID-19 disease. In particular, these are:
 - 33.5.1 frontline healthcare workers, particularly in regions where there is COVID-19 in the community (or regions that are at high risk of further spread of COVID-19);
 - 33.5.2 all those who are aged 65 years or over;
 - 33.5.3 Māori and Pacific People aged 50 years and over; and
 - 33.5.4 anyone over the age of 18 with comorbidities (these have been listed and provided to CVIP), with the exception of pregnant people, who completed a full primary course of vaccination in early pregnancy.
 - 33.6 AstraZeneca can also be used as a booster dose if available for specific situations including if an individual has had a significant adverse reaction after a previous Pfizer vaccine dose (e.g., anaphylaxis, myocarditis), and if AstraZeneca is not contraindicated.

- 34 CV TAG will continue to monitor all relevant information (including vaccine efficacy data against emerging variants of concern and emerging evidence on the duration of immunity) and will update their recommendations as further evidence becomes available.

Proceeding with the rollout of a booster programme from 29 November 2021

- 35 I am recommending that Cabinet agree to proceed with a booster programme from 29 November 2021.
- 36 This will ensure individuals who have received their primary course over 6 months ago receive a booster dose and are able to benefit from the extended duration of protection and improve existing overall immunity against the Delta variant. This will be critical as we move toward the new COVID-19 Protection Framework and we see higher rates of community transmission. Providing a booster programme will alleviate some of the impact for those population groups most at risk.
- 37 The growing complexity and diversification of vaccination status and need across the population has also reiterated the importance of a maintaining an efficient, equitable, safe, and positive experience for New Zealanders to ensure the success of the Immunisation Programme not only in 2021 but also the future as the context of programme delivery evolves. This reflects both the uncertainty around COVID-19 and the evolving risks, but also our developing understanding of the effectiveness of vaccines.
- 38 I am recommending to Cabinet, taking account of the recommendations from CV TAG, that:
- 38.1 CVIP will continue to focus efforts on increasing uptake and coverage across at-risk groups, specifically for Māori and Pacific people, success in this area is vital and the current outbreak continues to reiterate the importance of getting people vaccinated with their primary course;
 - 38.2 a booster dose is available for all eligible people 18 years of age and over, at least six months after their second dose (in line with regulatory approval by Medsafe);
 - 38.3 the roll out of the booster programme will be led by the necessary six-month interval between the primary course and the booster dose, essentially matching actual administration of the primary course in 2021;
 - 38.4 that CVIP will work with DHBs to ensure there is clear and consistent messaging on boosters, eligibility and their importance for the people most at risk (as noted by CV TAG); and
 - 38.5 the booster programme will be measured against the existing Success Framework and that CVIP will adjust planning as necessary to account for the booster programme to ensure that we are achieving high levels of uptake across at-risk groups.

- 39 Given available supply in Q4 2021 and Q1 2022 (discussed in the following section) and existing capacity in the Immunisation Programme to administer doses there is unlikely to be any need to prioritise people once they become eligible.
- 40 CV TAG have also recommended that AstraZeneca can be used as a booster dose. AstraZeneca is not currently approved by Medsafe for use as a booster. Further work is necessary to ensure that we able to roll out heterologous or mixed doses safely and effectively, subject to Medsafe approval. s 9(2)(f)(iv)

[REDACTED]

Supply and uptake considerations

- 41 Initial supply of the Pfizer vaccine was constrained in 2021 and the rollout was sequenced to manage supply and protect those most at risk first. However, the context is now different:
- 41.1 supply is less of a constraint as global manufacturing has increased (this is discussed in the following section);
 - 41.2 the CVIP has built the necessary infrastructure and capacity administer vaccines at scale to all New Zealanders;
 - 41.3 a significant proportion of the population have been vaccinated against COVID-19 and are well protected against the risks of COVID-19;
 - 41.4 we are transitioning to a state of play where we manage COVID-19 within New Zealand, and we will need to protect those most vulnerable or likely to be exposed to COVID-19 on an ongoing basis.

- 42 s 9(2)(j)
- [REDACTED]

- 43 In the coming months there will be a number of demands on our available supply of the Pfizer vaccine, including:
- 43.1 continued uptake of the Pfizer vaccine by unvaccinated individuals, those who have received only one dose, or people who are ageing into the eligible population;
 - 43.2 people with at least 6 months since their second dose the Pfizer vaccine who would be eligible for a third dose (as of 4 November);
 - 43.3 people over Q1 and Q2 who will become eligible for a booster dose following a 6-month interval;

43.4 the possible extension of eligibility to children 5 to 11 years of age, subject to regulatory approval and consideration by CV TAG and Cabinet (an application to Medsafe is expected from Pfizer in November 2021), with supply of paediatric doses likely available from January 2022; and

43.5 support for the Realm, Polynesia and if supply is available, the wider Pacific.

44 Modelling by CVIP and the Ministry of Health is shown in Table 2. There is sufficient supply overall for our likely vaccination needs in 2022. § 9(2)(f)(iv)

Table. Supply requirements and delivery schedule

	2021	2022			
	Q4	Q1	Q2	Q3	Q4
Supply requirements					
Administered Doses - 5-11 Years (Incl. Polynesia)	-	§ 9(2)(j)	-	-	-
Administered Doses - Adult (Incl. Polynesia)	1,188,250	§ 9(2)(j)	§ 9(2)(j)	-	-
Administered Doses - Total (Incl. Polynesia)	1,188,250*	§ 9(2)(j)	§ 9(2)(j)	-	-
Existing Doses End of 2021	2,619,750	-	-	-	-
Delivery					
Current Delivery Schedule	3,832,250	§ 9(2)(j)			
Ideal Delivery					
5-11 Year Doses	-	§ 9(2)(j)			
Adult Doses	-	-	§ 9(2)(j)		
Total	-	§ 9(2)(j)		-	-

*around 460,000 doses in Q4 are boosters with remaining doses required to reach 95 percent

45 Early discussions with Pfizer suggest that changes to the current expected delivery schedule should be manageable to support our population's needs. The context for securing a preferred delivery schedule is different from early 2021, due to the significant scaling up of manufacturing by vaccine suppliers § 9(2)(f)(iv)

46 However, proceeding with a booster programme now will ensure that those most at risk from COVID-19 are able to receive a third dose in the coming months and into Q1 of 2022.

55 Our efforts to support booster campaigns in the Pacific should factor in the specific needs of Pacific island countries, which will vary across the region. Some countries may require significant additional support from New Zealand Health officials to prepare to receive the Pfizer vaccine. Many are still rolling out first and second doses, and it is likely they will require further support for their primary campaign, including to access doses for paediatrics, before they are ready to consider boosters. There may be significant volumes of the Pfizer vaccine available for boosters from other donors, including Australia, and any support New Zealand provides would need to be closely coordinated with other donors' efforts.

56 ~~s 9(2)(f)(iv)~~
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57 I am seeking your agreement that:

57.1 we provide the Pfizer vaccine to the Realm for use as a booster in line with the advice and timing of our domestic booster programme and any regulatory requirements (e.g., a six-month interval between the primary course and the booster dose and for people 18 years of age or over);

57.2 ~~s 9(2)(f)(iv)~~
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58 ~~s 9(2)(f)(iv)~~
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59 ~~s 9(2)(f)(iv)~~
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Financial Implications

60 ~~s 9(2)(f)(iv)~~
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61 Donation to the Pacific will be subject to confirmation of interested countries on volumes required, ensuring there is sufficient supply and that all the necessary

arrangements are in place to utilise the Pfizer vaccine. s 9(2)(f)(iv)
[REDACTED]
[REDACTED]
[REDACTED] s 9(2)(f)(iv)
[REDACTED]
[REDACTED] We will monitor the budget implications of any other potential donations and report back to Ministers.

62 The cost of purchasing the additional Pfizer booster and paediatric doses has already been confirmed and appropriated for and will not require additional funding.

Legislative Implications

63 There are no legislative implications arising from the recommendations in this paper.

Population Implications

64 There are a number of population implications that should be noted that relate to the proposal to proceed with a booster dose as outlined in this paper (see table 2 below).

Table 2. Population implications

Population	How these proposals may affect this group
Unvaccinated	<p>11.9% of eligible population Unvaccinated individuals are at significantly higher risk of severe disease and hospitalisation when compared to the vaccinated. Furthermore, Māori and Pacific people’s vaccination rates lag that of the rest of the population, across all age bands. Māori and Pacific people are already at higher risk of severe disease.</p> <p>The proposals in this report include utilising the same pool of resources the primary immunisation efforts utilise, with the potential impacts on reaching vulnerable unvaccinated populations. To manage this emphasis is continues to be placed on focusing resources on continued primary immunisation efforts. There is sufficient supply and capacity to administer vaccines across the population.</p>
Māori	<p>56.6% fully vaccinated; 74.1% single dose Māori are at significantly higher risk of severe disease and hospitalisation, than non-Māori. Given the six-month interval required between the primary course and booster dose, administration of boosters will follow the rollout from 2021. However, the CVIP and DHBS will focus on achieving high uptake and equitable coverage of booster doses as people become eligible to ensure that we maintain a successful programme as more evidence emerges on vaccine effectiveness and the risk of COVID-19.</p>
Pacific Peoples	<p>72.3% fully vaccinated; 86% single dose *As above</p>

Children and young person	<p>73.7% fully vaccinated; 82.3% single dose (of currently eligible)</p> <p>The proposals in this vaccine include utilising vaccine doses and implementation resources that will also be utilised if a paediatric immunisation programme is agreed as well as ongoing efforts to reach unvaccinated eligible young people in 2021 and 2022.</p> <p>Children and young people under the age of 18 are not eligible for a booster dose. However, the risk of severe disease or death for children is far lower and the duration of protection provided by two doses of the Pfizer vaccine is likely to be longer based on emerging evidence. There will be sufficient supply and capacity to administer booster doses to those who are eligible or if eligibility is extended.</p>
Older persons (65+)	<p>95.9% fully vaccinated; 95.4% single dose</p> <p>Older persons have some of our highest vaccination rates, however, due to their age and time since primary vaccine course, are most likely to have waning immunity from the vaccine. Proposals in this paper are designed to address this population by providing boosters as they become eligible.</p>

Human Rights

65 [REDACTED]

66 This response is proportionate and based on the original evidence and decision-making frameworks underpinned by the principle of equity used for the primary vaccine roll-out in 2021, with any discrimination in favour of people at greater risk.

67 It is important to note that we have purchased enough vaccines for every person in New Zealand. All people are equally deserving of care, but the 6-month interval will dictate the prioritisation of booster delivery.

Consultation

68 The Ministry of Health has consulted with the Treasury and the Ministry of Foreign Affairs and Trade. The Department of the Prime Minister and Cabinet has been informed.

Communications

69 Subject to Cabinet's agreement on the decision to proceed with a booster programme; the key messaging on this decision is:

69.1 we are continuing to focus on primary Immunisation Programme delivery to all those 12+, with the intention of achieving broad coverage of vaccine-induced immunity and reaching 90 percent uptake across New Zealand;

69.2 a booster programme will start from 29 November for all people who are 18 years or older and received their second dose at least 6 months ago;

- 69.3 we have sufficient supply to proceed with a booster programme alongside providing first and second doses;
- 69.4 we are focused on achieving high uptake of the booster dose for those who are at highest risk of waning immunity, severe illness, and exposure to COVID-19.
- 70 Officials are preparing messaging to support announcements on 15 November 2021 and ensure that there is transparent and consistent communication on the decision to proceed with a booster programme.

Proactive Release

- 71 We intend to proactively release this Cabinet paper within 30 working days, with redactions as appropriate under the Official Information Act 1982.

Recommendations

The Minister for COVID-19 Response recommends that the Committee:

- 1 note that evidence is growing that the vaccine-induced immunity to COVID-19 wanes over time, particularly after 6 months from the second dose;
- 2 note that evidence and international practices demonstrate the efficacy and value of a booster COVID-19 vaccines in restoring protection, particularly for those people at greater risk from COVID-19;
- 3 note that Medsafe has approved the use of the Pfizer COVID-19 vaccine as a booster (third dose) for people who are 18 years or older and have had a minimum six-month interval following their second dose;
- 4 note that CV TAG have provided technical advice on the use of the Pfizer vaccine as a booster
- 5 agree that the primary focus of the COVID-19 vaccine immunisation programs remains on increasing uptake of the first and second dose of the Pfizer vaccine;
- 6 agree to proceed with the use of the Pfizer COVID-19 vaccine as a booster dose for the COVID-19 Vaccine and Immunisation Programme;
- 7 note that the six-month interval will establish roll out of the vaccine based on when people received the vaccine in 2021;
- 8 agree to align the booster programme with the COVID-19 Vaccine Technical Advisory Group recommendations on those most at risk:
- 8.1 CVIP will continue to focus efforts on increasing uptake and coverage across at-risk groups, specifically for Māori and Pacific people, success in this area is vital and the current outbreak continues to reiterate the importance of getting people vaccinated with their primary course;
- 8.2 a booster dose is available for all eligible people 18 years of age and over, at least six months after their second dose (in line with regulatory approval by Medsafe);

- 8.3 the roll out of the booster programme will be led by the necessary six-month interval between the primary course and the booster dose, essentially matching actual administration of the primary course in 2021;
 - 8.4 that CVIP will work with DHBs to ensure there is clear and consistent messaging on boosters, eligibility and their importance for the people most at risk (as noted by CV TAG); and
 - 8.5 the booster programme will be measured against the existing Success Framework and that CVIP will adjust planning as necessary to account for the booster programme.
- 9 note that Cabinet has previously agreed [CAB-21-MIN-0350 refers] that:
- 9.1 New Zealand will continue to support the Cook Islands, Niue and Tokelau to access sufficient vaccines to cover their ongoing immunisation needs in 2022; and
 - 9.2 New Zealand will work with other donors to support Samoa, Tonga, Tuvalu and Fiji to access sufficient vaccines to cover their ongoing immunisation needs in 2022;
- 10 note that officials will engage directly with Pacific counterparts to understand their immunisation needs for 2022 and scope possible areas where New Zealand can provide support;
- 11 agree that New Zealand will begin to donate Pfizer vaccine from our portfolio to the Realm for use as boosters in line with Medsafe’s regulatory decision, and in line with the timing of our domestic booster campaign;
- 12 **s 9(2)(f)(iv)** [REDACTED]
- [REDACTED]

Authorised for lodgement

Hon Chris Hipkins
Minister for COVID-19 Response