Briefing

Postponing commencement of new arrangements at the air border

Date due to MO:	8 January 2022	**Action required by:**	10 January 2022
Security level:	IN CONFIDENCE	**Health Report number:**	20220003
To:	Hon Grant Robertson, Acting Minister for COVID-19 Response		

Contact for telephone discussion

Name	Position	Telephone
Stephen Harris	Group Manager, COVID-19 Policy	s 9(2)(a)
Robyn Shearer	A/g Director-General	s 9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Postponing commencement of new arrangements at the air border

Security level:	IN CONFIDENCE	**Date:**	8 January 2022
To:	Hon Grant Robertson, Acting Minister for COVID-19 Response		

Purpose of report

1. This report recommends that, based on a public health risk assessment undertaken on 5 January 2022, you postpone commencement of the COVID-19 Public Health Response (Air Border Order) 2021 and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021.

2. The report also recommends that you:

   a. consult on the proposal in this paper with the Prime Minister, the Minister of Justice, the Minister of Health and the Minister of Transport

   b. agree that the Ministry issue drafting instructions to the Parliamentary Counsel Office (PCO) to draft the required amendments

Summary

3. In December 2021, Cabinet agreed to commence the Reconnecting New Zealanders programme with a staged reopening of New Zealand's borders, starting at 11.59pm on 16 January for certain travellers from Australia.

4. Legislation was developed to give effect to that decision. The COVID-19 Public Health Response (Air Border) Order 2021, and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021 were both signed by Minister Hipkins on 23 December 2021.

5. Both Orders facilitate the opening of New Zealand's borders and were designed for that specific purpose. Accordingly, a number of the provisions within them provide for looser risk mitigation controls at the air border than those that are currently in place. For example, in relation to aircrew:

   a. International aircrew are currently required to go into MIQ for the period they are in NZ. The new ABO would not require international aircrew to isolate if they meet a number of conditions.

   b. NZ-based aircrew who have been overseas for more than 7 days are currently required to go into MIQ for 10 days, the new ABO would not require this.

   c. NZ-based aircrew on higher-risk routes are currently required to self-isolate and get tested after 48 hours, then to remain in isolation until a negative result is returned. The new ABO would not require this.

6. While some of these changes could be effected under the new Order, the distinctions in the current settings are not drafted into the new Order, and the Key safety standards

themselves are changed in the new ABO. The key safety standards are required to be followed by NZ-based aircrew while overseas.

7. Since those decisions were made, the Omicron variant has spread rapidly around the world, particularly in countries from which a high proportion of travellers to New Zealand start their journey, such as Australia, the United Kingdom and the Unites States. However, to date, Omicron has not been seeded in the community in New Zealand.

8. In response to this new threat, Ministers have subsequently decided to defer the reopening of New Zealand's border to 27 February 2022. This allows time for a greater proportion of New Zealand's population to receive a booster vaccination, for vaccination of 5 – 11 year olds to be well advanced, and for community-based mitigation measures to be implemented.

9. The Ministry of Health undertook a public health risk assessment (PHRA) on arrangements at the air border on 5 January 2022 (**Annex 1**). The PHRA found that our existing measures at the border were working well, and that additional testing measures introduced recently will strengthen these[1].

10. One further recommended measure is postponing new arrangements for aircrew, which are due to commence from 11.59pm 16 January, as part of the COVID-19 Public Health Response (Air Border) Order 2021 and the changes made by the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021; because moving to the new settings at that time would pose a higher risk of introducing Omicron into the community in New Zealand than retaining the existing settings.

11. It is impractical to defer commencement of only these provisions in the Orders, as this would require substantial redrafting of the Orders, which is not likely to be feasible prior to 16 January. It is therefore recommended that you agree to postpone commencement of the entirety of both Orders.

12. Unless the legislation is deferred as suggested, there is a higher and increasing risk that aircrew will unintentionally provide a vector for community transmission of Omicron into New Zealand.

13. Our recommendation is to postpone the commencement of both amendments to 27 February 2022. This would again align the commencement of these Orders with the expected commencement date for the first stage of the Reconnecting New Zealanders medium-risk pathways plan, namely to allow MIQ-free entry into self-quarantine at home for fully vaccinated New Zealanders and eligible class visa holders.

14. Due to the increasing pressures on MIQ capacity, we will need to amend the current Orders to continue to give effect to some necessary changes that would have otherwise come into effect on 16 January. This includes amending the meaning of "aircrew" to limit the staff that airlines can direct to NZ without an MIQ allocation.

15. Initial consultation on this approach with relevant government agencies including the Department of Prime Minister and Cabinet, Ministry of Foreign Affairs and Trade, the Ministry of Transport, the Ministry of Business, Innovation and Employment and Customs NZ has received in principle support for the proposed deferral, and the recommended

[1] **The two additional measures are the reduction in pre-departure test times from 72 hours to 48 hours; and the introduction of the ability to use a RATor LAMP test 24 hours prior to departure as an option for travellers**

commencement date. Consultation has also been undertaken with airlines and with the Board of Airline Representatives of New Zealand, which have raised no significant concerns.

16. Subject to your approval, the Ministry will instruct the Parliamentary Counsel Office to prepare a draft Order for your signature to amend the commencement date of the COVID-19 Public Health Response (Air Border) Order 2021 and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021.

17. The Ministry is intending to undertake a further public health risk assessment on risk control measures at the air border on 27 January 2022. However, this assessment may be brought forward, if it is necessary to consider any emerging issues earlier.

Recommendations

I recommend you:

a)	**Note** that the Omicron variant has spread rapidly throughout the world since key policy decisions relating to New Zealand's air border were made in December 2021.	**Noted**
b)	**Note** the renewed importance of keeping out the virus, to allow for a greater proportion of New Zealand's population to receive a booster shot, to enable the vaccination programme for 5 to 11 year olds to be well advanced, and to better prepare the health system for the expected high caseloads once Omicron is spreading in the community.	**Noted**
c)	**Note** the public health advice that new settings for aircrew which were due to commence at 11.59pm 16 January as part of the COVID-19 Public Health Response (Air Border) Order 2021 and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021 should be postponed, as moving to these arrangements at that time would increase the risk of introducing Omicron into the community.	**Noted**
d)	**Agree** to postpone the commencement of the entire COVID-19 Public Health Response (Air Border) Order 2021 and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021, as it is not feasible to postpone commencement of only those provisions relating to aircrew in this legislation	**Yes/No**
e)	**Agree** that the date of entry into force be 27 February 2022, to align with the expected date for the first stage of the Reconnecting New Zealanders medium-risk pathways plan, in which fully vaccinated New Zealand citizens would be able to travel from Australia to New Zealand without entering managed isolation and quarantine on arrival.	**Yes/No**
f)	**Agree** that due to the increasing pressures on MIQ capacity, the Ministry issue drafting instructions to PCO to amend the current Orders to continue to give effect to some necessary changes that would have otherwise come into effect on 16 January. This includes amending the meaning of "aircrew" to limit the staff that airlines can direct to NZ without an MIQ allocation.	**Yes/ No**

g)	**Note** that this proposed postponement, and the recommended revised date has been consulted with relevant government agencies, and initial discussions have been held with industry stakeholders.	**Noted**
h)	**Agree** to consult on the proposal in this paper with the Prime Minister, the Minister of Justice, the Minister of Health and the Minister of Transport and to report back on the outcome of ministerial consultation by Tuesday 11 January 2022.	**Yes/ No**
i)	**Agree,** subject to the outcome of your consultation with other Ministers, that the Ministry of Health issue drafting instructions to the Parliamentary Counsel Office to defer commencement of COVID-19 Public Health Response (Air Border) Order 2021 and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021 to 27 February 2022	**Yes/ No**
j)	**Note** that the Ministry of Health will undertake a further public health risk assessment on risk control measures at the air border on 27 January 2022, subject to the proviso that we may need to undertake an earlier review if necessary, in the context of any emerging issues.	**Noted**

Robyn Shearer
Acting Director-General of Health

Date: 07.01.2022

Hon Grant Robertson
Acting Minister for COVID-19 Response

Date:

Postponing commencement of new arrangements at the air border

Background

18. In December 2021, the Ministry of Health (Ministry) reviewed the public health risk mitigation measures at the border to determine if they were fit for purpose. It was determined that they were.

19. At that time, Cabinet had agreed that we would re-commence the opening of New Zealand's borders by enabling people to return to New Zealand from Australia without the need for quarantine from 11:59pm on Sunday 16 January 2022.

20. The legislation governing risk control measures at the air border, the Air Border Order (ABO), was re-written to facilitate that change. The new ABO was signed on 23 December and is due to come into effect at 11:59pm on Sunday 16 January. Amongst other things, the new ABO provides lesser controls on the movements of aircrew coming into New Zealand, including removing the requirement that international aircrew go directly into an MIQ facility.

21. Since then, the situation with Omicron has been rapidly changing. Cases of Omicron have soared around the globe. In New South Wales, Australia, for example, cases have surpassed 35,000 per day. In response to this changing international context, Cabinet agreed to defer the commencement of the Re-Connecting New Zealanders programme until 27 February 2022.

22. We have recently seen an influx of Omicron cases at the border. Between 1 December and 6 January, there were 292 cases reported at the border. 127 of these were confirmed Omicron cases, with 130 awaiting whole genome sequencing. During this time only 8 Delta cases were detected.

23. The last week has seen the highest number of cases reported at the border since MIQ became mandatory. On 6 January there were 43 new cases reported at the border (i.e., in MIQ), which were more than double the 19 reported new community cases.

24. The number of Omicron cases crossing the border is increasing with current predictions estimating between 50 and 70 cases per week from the 3 main source countries (Australia, United States and the United Kingdom). An additional 10 – 20 cases are expected per week from transit countries including the UAE, Qatar and Singapore. These numbers are expected to increase over coming weeks.

25. Omicron has a shorter incubation period than Delta and is more transmissible. In each Australian state with an Omicron outbreak new cases are doubling every 2 to 4 days.

We have robust health and safety standards pre departure, at the border and on arrival in New Zealand

26. On Wednesday 5 January 2022, a public health risk assessment was conducted to re-assess our border settings to see whether anything further might be done to delay the arrival of Omicron at our borders (see the first table attached to **Annex 1**)

27. We currently have a significant number of public health measures in place for travellers to mitigate against the importation of COVID-19 to Aotearoa New Zealand. Included in **Annex 1** is a table setting out all current measures in place.

28. Based on this review, I consider that these measures continue to work well.

Introduction of RATs/LAMP 24 hours prior to departure as an option for some travellers

29. From 11.59pm on 6 January 2022, travellers from certain countries have been able to undertake a rapid antigen test (RAT) or loop-mediated isothermal amplification (LAMP) test within 24 hours of departure, where PCR testing within 48 hours of departure is not likely to be practical.

30. Initially, these arrangements were introduced as a temporary exemption to pre-departure testing requirements under the COVID-19 Public Health Response (Air Border) Order 2020, with more enduring arrangements to be made under the COVID-19 Public Health Response (Air Border) Order 2021, once it has commenced.

31. It is anticipated that they will further strengthen New Zealand's border controls, however there has not yet been an opportunity to assess their impact on the arrival of travellers with Omicron at the border.

Arrangements for aircrew

32. There are a number of public health measures currently in place to manage the risks posed by both NZ domiciled aircrew and international aircrew.

33. These settings are due to change on 16 January 2022, when the COVID-19 Public Health Response (Air Border) Order 2021 and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021 commence.

34. Table Two in **Annex 1** sets out the current and future settings for aircrew. Of particular note is that international aircrew will move from being required to go into MIQ on their arrival in New Zealand, to be being able to go directly into the community provided they meet certain pre-requisites.

35. The Ministry has assessed these new settings in relation to aircrew in the context of Omicron outbreaks around the world and considers that moving to these settings on 16 January 2022 would present a higher and increasing risk of importation of Omicron into the community. Over the past two weeks we have seen two cases of aircrew infections in New Zealand and numerous cases have emerged in Australia.

36. Given that our current strategy is to keep Omicron out of New Zealand for as long as possible, I recommend delaying the new settings for aircrew, and instead continuing all current legislative settings for both NZ domiciled aircrew and international aircrew until 27 February 2022, so that the enactment of the new ABO continues to align with the opening of our borders under the Re-Connecting New Zealand strategy.

37. The settings relating specifically to aircrew will be further reviewed, along with our other border risk mitigation measures, on 27 January 2022, subject to the proviso that we may need to undertake an earlier review if necessary in the context of any emerging issues.

38. In the interim, the Ministry will also work across agencies and with the airlines to explore options for additional public health measures in relation to NZ domiciled aircrew. These could include additional testing or use of PPE on a voluntary basis. No additional legislative changes are proposed at this time to support these measures.

The COVID-19 Public Health Response (Air Border) Order 2021 will need to be amended

39. On 23 December 2021, the Minister for COVID-19 Response signed the COVID-19 Public Health Response (Air Border) Order 2021 and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021to facilitate opening our borders to travellers from Australia from 11:59pm on 16 January 2022. In light of the prevalence of the Omicron variant in Australia and elsewhere, Ministers subsequently decided to defer the re-opening of the borders until 27 February 2022.

40. In order to retain existing settings for aircrew, these Orders will need to be amended to defer the commencement date. The Ministry considered whether it would be feasible to only postpone certain provisions of the Orders, however it would not be possible to make the necessary changes to the Orders in the time available, due to the complexity of the legislative drafting required.

41. For this reason, it is recommended that you agree to postpone the entire COVID-19 Public Health Response (Air Border) Order 2021 and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021 to 27 February 2021, to align with the expected start date for the first stage of the Reconnecting New Zealanders plan.

42. Other existing arrangements under the COVID-19 Public Health Response (Air Border) Order 2020 will also be extended to 27 February 2022. This includes the Director-General's exemption for travellers from certain countries from pre-departure testing requirements, which has been used on a temporary basis to allow the use of RAT or LAMP tests within 24 hours of departure, as an alternative to PCR testing within 48 hours.

Required amendments to the current Orders prior to 27 February 2022

43. Because the COVID-19 Public Health Response (Air Border) Order 2021 and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021 each included important changes that now will not be coming into effect on 16 January as intended, we propose to make amendments to the current Orders to continue to give effect to those necessary changes.

44. One change that is required is to give effect to the new definition of "aircrew" that would otherwise have taken effect on 16 January 2022. This amendment is required to alleviate pressure in an increasingly burdened MIQ system, ensure the MIQ system is equitable, and provide further barriers to the arrival of Omicron.

45. Under the current Orders, NZ domiciled aircrew can come into MIQ without an MIQ allocation, even if they are entering outside their capacity as a pilot, co-pilot, or crew member if they are directed to by their airline. Unlike working aircrew who usually only stay in MIQ for 24 hours, these aircrew require 10-day MIQ stays, which is causing issues for the already stretched MIQ capacity. These aircrew cannot be planned for and may

displace other legitimate returnees or risk the arrival of Omicron if there is no MIQ capacity for them.

46. We recommend that you agree for the Ministry to issue drafting instructions to PCO to this effect. We are also working with PCO to give effect to decisions undertaken by the Minister prior to the Christmas break to amend the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2020 in order for a person's period of isolation or quarantine to end up to 6 hours early.

Consultation undertaken to date

47. Initial consultation on this approach with relevant government agencies including the Department of Prime Minister and Cabinet, Ministry of Foreign Affairs and Trade, the Ministry of Transport, the Ministry of Business, Innovation and Employment and Customs NZ has received in principle support for the proposed deferral, and the recommended commencement date.

48. The Ministry of Transport has advised airlines of the proposal to maintain the current aircrew settings, based on the public health assessment.

49. At the time of discussions, the approach was to extend until the end of January. In general, there was understanding and acceptance of the approach, although the proposed review in late January was welcomed as mitigating the most significant impacts.

50. Among these impacts is the requirement for New Zealand-domiciled crew to maintain the Key Safety Standards in overseas ports; the proposed changes were highly anticipated by crew and there are likely to be concerns if this is to be extended until the end of February, particularly if the health situation and balance of risk changes.

51. Air New Zealand has expressed strong interest in working with the Ministry of Health and agencies on any new measures for New Zealand-domiciled crew, including how additional tested might be implemented.

52. The Ministry of Health will work with the Ministry of Transport to continue to engage with key stakeholders in the aviation sector.

Next steps

53. You are required to consult the Prime Minister, Minister of Justice and Minister of Health on the proposed approach to defer commencement of the COVID-19 Public Health Response (Air Border) Order 2021 and the COVID-19 Public Health Response (Isolation and Quarantine and Other Matters) Amendment Order 2021 to 27 February 2022. We recommend that you also consult with the Minister of Transport.

54. If you agree, the following timelines will need to apply:
    - Ministerial consultation Sunday 9 January to Monday 10 January 2022 (48 hours)
    - Signature version of the amendments provided to your office Wednesday 13 January 2022
    - Final amendments signed no later than 3pm Thursday 14 January 2022
    - Amendments gazetted no later than 5pm Thursday 14 January 2022
    - Amendments in force by 5pm Sunday 16 January 2022.

MINISTRY OF HEALTH
MANATŪ HAUORA

Memorandum: Public Health Risk Assessment of Air Border Risk Mitigation Controls

To:	Robyn Shearer, A/g Director-General of Health
From:	Dr Caroline McElnay, Director of Public Health
Date:	6 January 2022
For your:	Decision

Purpose of report

1. This memo provides you with a Public Health Risk Assessment (PHRA) of the border settings to mitigate the risk of the Omicron variant COVID-19 entering New Zealand and spreading within the community.
2. The memo recommends that you agree to advising the Minister to amend the COVID-19 Public Health Response (Air Border) Order 2021 (2021 ABO) to continue all current legislative settings for both New Zealand domiciled aircrew and international aircrew. These settings would be further reviewed on 31 January 2022.
3. The memo also notes that we will work across agencies and with the airlines to explore options for additional public health measures in relation to NZ domiciled aircrew. These could include additional testing or use of PPE on a voluntary basis. We are not proposing additional legislative measures arising out of this yet.

Background

4. In December 2021 the Ministry of Health (Ministry) reviewed the public health risk mitigation measures at the border to determine if they were fit for purpose. It was determined that they were.
5. Since then, the situation with Omicron has been rapidly changing. Cases of Omicron have soared around the globe. In New South Wales, Australia, for example, cases have surpassed 35,000 per day.
6. We have recently seen an influx of Omicron cases at the border.
7. Since 1 December there have been 292 cases reported at the border. 127 of these are confirmed Omicron cases with 130 awaiting whole genome sequencing. During this time only 8 Delta cases have been detected.

8. The last week has seen the highest number of cases reported at the border since MIQ became mandatory. On 6 January there were 43 new cases reported at the border (i.e. in MIQ), which were more than double the 19 reported new community cases.

9. The number of Omicron cases crossing the border is increasing with current predictions estimating between 50 and 70 cases per week from the 3 main source countries (Australia, United States and the United Kingdom). An additional 10 – 20 cases are expected per week from transit countries including the UAE, Qatar and Singapore. These numbers are expected to increase exponentially over coming weeks.

10. Omicron has a shorter incubation period than Delta and is more transmissible. In each Australian state with an Omicron outbreak new cases are doubling every 2 to 4 days.

We have robust health and safety standards pre departure, at the border and on arrival in New Zealand

11. On Wednesday 5 January a Public Health Risk Assessment (PHRA) was conducted to re-assess our border settings to see whether anything further might be done to delay the arrival of Omicron at our borders.

12. We currently have a significant number of public health measures in place for travellers to mitigate against the importation of COVID-19 to Aotearoa New Zealand. Attached as **Annex 1** is a table setting out all current measures in place.

13. We have reviewed these settings and have determined that they continue to work well.

Introduction of RATs/LAMP 24 hours prior to departure as an option for travellers

14. On 4 January 2022, the Acting Minister for COVID-19 Response, Dr Ayesha Verrall, agreed in consultation with Minister Hipkins with the recommendation of the Director General of Health that the use of rapid antigen tests (RATs) or loop-mediated isothermal amplification (LAMP) testing if done within 24 hours of departure would be an appropriate alternative to PCR testing for travellers arriving by air in New Zealand to meet pre-departure testing (PDT) requirements.

15. The policy decision will be implemented in three steps:

    a) **From 11.59pm 6 January 2022** – the Director-General of Health will exempt travellers from certain countries from the PDT requirements of the COVID-19 Public Health Response (Air Border) Order 2020, and impose conditions on travellers from some countries to comply with alternative testing requirements.

    b) **From 11.59pm 16 January 2022** – the COVID-19 Public Health Response (Air Border) Order 2021 will come into force, allowing for the detailed requirements of testing types and time periods to be specified by the Director-General of Health. It is expected that there will be a need to exempt travellers from some countries from PDT requirements from this date as well (for example, for countries that remain COVID free).

c) **Future changes to the COVID-19 Public Health Response (Air Border) Order 2021** – the Ministry will shortly commence work on a further potential suite of changes to the COVID-19 Public Health Response (Air Border) Order 2021 and related legislation. It is anticipated that as part of this work, provisions relating to PDT will be amended to reflect the recent policy decision. This work will commence from 10 January 2022.

16. These new measures are not yet in force, and so we have not yet had an opportunity to assess how they will impact on the arrival of Omicron at the border. We anticipate that they will further strengthen our border controls..

Air crew

17. We have a number of public health mitigation measures currently in place to manage the risks posed by both NZ domiciled aircrew and international aircrew. Attached as **Annex 2** is a table of all the public health measures that we currently have in place for aircrew to prevent the importation of COVID-19.

18. In anticipation of the re-opening of the borders as a part of the Reconnecting New Zealanders strategy, the ABO was amended on 23 December to enable revised settings for aircrew to come into effect on 16 January 2022. These new settings are also included in the table at Annex 2.

19. We have considered the new settings in the ABO in relation to aircrew and advise that moving to these settings on 16 January 2022 would present a higher and increasing risk of importation of Omicron into the community. Over the past two weeks we have seen two cases of aircrew infections in New Zealand and numerous cases have emerged in Australia.

20. Given that our current strategy is to keep Omicron out of New Zealand for as long as possible, I recommend delaying the new settings for aircrew, and instead continuing all current legislative settings for both NZ domiciled aircrew and international aircrew.

21. These settings will be further reviewed, along with our other border settings, on 27 January 2022, subject to the proviso that we may need to undertake an earlier review if necessary in the context of any emerging issues.

22. In the interim, we will also work across agencies and with the airlines to explore options for additional public health measures in relation to NZ domiciled aircrew. These could include additional testing or use of PPE on a voluntary basis. We are not proposing additional legislative measures arising out of this yet.

The 2021 Air Border Order will need to be amended

23. On 23 December 2021, the Minister signed a new Air Border Order to facilitate opening our borders to travellers from Australia from 11:59pm on 16 January 2022. In light of the

prevalence of the Omicron variant in Australia and elsewhere, Ministers subsequently decided to defer the re-opening of the borders until 27 February 2022.

24. To retain the current aircrew settings, the commencement date for the new Air Border Order will need to be deferred. Separate advice on this is being prepared for ministerial consideration over the coming weekend. That advice will propose that the commencement of the new Air Border Order be deferred to 27 February 2022 to continue its alignment with the re-opening of the borders (now also shifted to 27 February 2022).

25. This does not affect the timing for our ongoing review of public health settings at the border, the next one of which is scheduled for 27 January 2022 (subject to the proviso that we may need to undertake an earlier review if necessary in the context of any emerging issues).

Additional Public Health measures

26. MIQ is reaching capacity and if border cases were to remain high there might no longer be space available for community cases. This could exacerbate management of the current community Delta outbreak.

27. From a purely Public Health perspective, the only remaining public health tool would be to consider reducing the inflow of travellers. I note that this approach could have significant wider implications and therefore I am not recommending it at this stage. Given the broad implications of any reduction in the flow of travellers, any work to investigate additional options would need to be led at an all of government level.

28. Instead, I recommend that we allow the additional measures set out at paragraph 14 above to be implemented and consider what further action might be required once their impact has been appropriately assessed.

Recommendations

I recommend that you:

a)	**Note** that on Wednesday 5 January 2022, a Public Health Risk Assessment reviewed New Zealand's border settings in light of the increased risk posed by the Omicron variant of COVID-19.	**Noted**
b)	**Note** that the Public Health Risk Assessment held on 5 January 2022 found that our current border controls are working well in managing the risk of importing COVID-19 through the air border.	**Noted**
c)	**Note** that additional testing safeguards at the air border will shortly commence, and that these are expected to further increase the strength of our border controls.	**Noted**
d)	**Note** that the COVID-19 Public Health Response (Air Border) Order 2021 comes into force at 11.59 on 16 January 2022, and that this Order	**Noted**

	contains new settings in relation to the management of aircrew crossing the New Zealand border.	
e)	**Note** that the Public Health Risk Assessment held on 5 January 2022 found that moving to the new settings for aircrew under the revised Air Border Order on 16 January 2022 would present a higher risk of the importation of the Omicron variant into the New Zealand community.	**Noted**
f)	**Agree** to recommend to the Minister that the COVID-19 Public Health Response (Air Border) Order 2021 be amended to continue current settings for aircrew.	**Agree**
g)	**Note** that in the interim we will work across agencies and with airlines to explore options for additional public health measures in relation to NZ domiciled aircrew	**Noted**
h)	**Note** a further Public Health Risk Assessment of border settings will be conducted on 27 January 2022, subject to the proviso that we may need to undertake an earlier review if necessary in the context of any emerging issues.	**Noted**

Signature _____ Date: 6 January 2022

Robyn Shearer
Acting Director-General of Health

Annex 1: Public health measures for travellers

Stage in a traveller's journey	Public health measures (for travellers)
In country of origin	• **Restrictions on the overall number of people crossing the border** – limits on the total number of travellers arriving in New Zealand also limit the number of travellers with COVID-19 • **Pre-departure testing** - almost all travellers are required to undertake COVID-19 testing prior to departure. This testing will generally be either a PCR test within 48 hours of departure. Travellers from certain countries can also comply with the requirement by undertaking a RAT or LAMP test within 24 hours of departure. Travellers must show written evidence of a negative result from their PDT at their point of departure and on arrival in NZ. Travellers from a small number of countries where there is no COVID in the community (or where any testing is impractical) are exempt from this requirement. • **Vaccination requirement** - non-NZ citizens travelling to, or transiting through, New Zealand are generally required to have completed the recommended course of an approved vaccine at least 14 days prior to departure <u>Additional measures currently being implemented:</u> • Establish of vaccination passports, to provide validated information about each travellers vaccination status
At point of departure	• **Basic infection prevention and control measures** – travellers in international airports throughout the world are generally required to adhere to a range of basic infection prevention and control practices while moving through the airport, including wearing a face covering and physical distancing
In flight	• **Basic infection prevention and control measures** – travellers on all scheduled international flights to New Zealand are required to wear a face covering while on board their plane, except when eating and drinking. Other basic infection and prevention controls are encouraged. • **Aircraft ventilation** - airlines utilise HEPA filtration to clean recirculated air on board aircraft.
At point of arrival	• **Basic infection prevention and control measures** – travellers arriving in New Zealand are required to adhere to a range of basic infection prevention and control practices while moving through the airport and in transit to their MIQF, including wearing a medical mask and physical distancing. Returnees are encouraged to put on a fresh medical mask on arrival at the airport and these are made available to returnees. Bus transfers are also required to comply with infection prevention and control measures. • **Investigation of use of HEPA filters in buses** – this could improve ventilation and reduce infection risk on vehicles used for transit of travellers from airports to MIQFs [I need to check this with MBIE as think this may have been completed] • **Initial health screening** – all returnees are subject to an initial health screening at the airport before transfer to a MIF
	• **Room restrictions** – returnees are generally required to remain in their rooms while at an MIQF, except for a limited number of reasons (such as routine testing, exercise or smoking). Returnees are not allowed to leave their rooms (except for testing) until they have returned a negative day 0/1 test. • **Routine testing of returnees** – returnees in an MIQF are PCR tested on or around day 1, day 3, day 6, and day 9 of their stay • **Transfer of positive cases to separate facilities or separate areas** – where a returnee in an MIF tests positive to COVID-19, they are transferred to dedicated facilities or separate areas for positive cases, to reduce the risk of

In MIQ	infecting other returnees. A range of infection prevention and control procedures are followed before, during and after any such transfer. • **Basic infection prevention and control measures** – returnees in an MIQF are required to adhere to a range of basic infection prevention and control practices when outside their room, including wearing a medical mask and physical distancing. All staff are required to wear N95 masks when in a red zone area (any area where returnees may go) and an additional requirement was placed on staff to wear medical masks in all green areas (non-returnee facing areas) just before Christmas 2021. • **Daily returnee health checks** – all returnees in an MIQF complete an initial health assessment within 48 hours of arrival in the MIF and regular health checks throughout their stay • **Cohorting** – returnees are grouped with other returnees who have arrived within a 96-hour period (except for a small number of facilities used for groups such as unaccompanied minors, aircrew and deportees), to reduce the risk of returnees at the end of their stay being infected by those commencing their stay • **Managed access to outdoor fresh air/exercise/smoking**– access to shared outdoor areas for fresh air, exercise or smoking breaks is managed in MIQFs. Off-site exercise is no longer offered. Nicotine replacement therapy is also offered to all returnees who smoke to reduce the number of movements outside rooms for smoking breaks. • **Window / Door opening protocols** – to avoid the risk of airborne spread in corridors, windows in a returnee's room must be closed before the door is opened • **Ventilation** – a ventilation programme was in place through 2021 to upgrade ventilation in all facilities. All quarantine rooms have an air filtration unit placed within them as well as there being air filtration devices in all shared spaces in all facilities. • **IPC audits** – IPC audits of all facilities are performed on a rolling quarterly basis with additional visits for any facilities where high risk findings are identified. • **Contact tracing** – contact tracing is undertaken for any border cases including review of CCTV of their transit from the airport to MIQ to identify any potential close contacts. <u>Additional measures currently being implemented:</u> • Returnee behavioural insights study to support improved education and procedures for returnees
Post release from MIQ	• **Public health advice to returnees upon departure -** written advice is provided to all travellers regarding remaining vigilant for symptoms, using the COVID-19 tracer app, self-isolating and getting tested if any symptom develops and complying with public health requirements generally. • **Post-departure testing (e.g. day 5 after departure)** – in certain cases, travellers may be asked to test several days after leaving an MIQF, such as where they may have been exposed late in their stay

Annex 2: Public Health measures for aircrew

PH mitigation measures for NZ domiciled aircrew		PH mitigation measures for international aircrew	
Current settings	Settings due to come into effect on 16 January	Current settings	Settings due to come into effect on 16 January

• Aircrew must adhere to the Key Safety Standards, which are designed to minimise the risk of infection while overseas
• On return to NZ, aircrew must:
  ○ Self-isolate at their nominated residence or other accommodation
  ○ Provide the address of their place of self-isolation and contact details
  ○ Undergo a medical examination and test
• Subject to an risk assessment by a medical officer of health, aircrew who have flown on designated higher risk routes, been outside NZ for seven consecutive days or have travelled domestically outside NZ may be required to self-isolate or enter managed isolation and quarantine on return to NZ
• NZ based aircrew must be vaccinated against COVID-19
• NZ based aircrew must regularly be tested for COVID-19
	• In order to be exempt from isolation and quarantine requirements, NZ-based aircrew must:
	  ○ be vaccinated, or excused by a medical certificate
	  ○ have a pre-departure test, or be excused by a medical certificate
	  ○ not be subject to public health direction in another country
	  ○ comply with the Key Safety Standards or a route safety plan
	  ○ make traveller declarations at certain times
	  ○ not exhibit COVID-19 symptoms
	  ○ wear face coverings in certain places
	  ○ undergo COVID-19 screening
	  ○ be considered to be a low risk of having or transmitting COVID-19
	  ○ maintain physical distancing
	• NZ based aircrew who do not meet these requirements are subject to isolation and quarantine requirements
	• NZ based aircrew must regularly be tested for COVID-19
		• Overseas based aircrew who arrive in NZ are subject to a health assessment.
		• Overseas based aircrew must either remain airside or enter a managed isolation and quarantine facility for the duration of their layover.
		• At all times, overseas based aircrew must comply with directions of a medical officer of health or health protection officer, including by physical distancing, wearing face coverings or wearing other PPE.
			• In order to be exempt from isolation and quarantine requirements, overseas based aircrew must:
			  ○ be vaccinated, or excused by a medical certificate
			  ○ have a pre-departure test and a negative result from that test, or be excused by a medical certificate
			  ○ not be subject to public health direction in another country
			  ○ comply with the Key Safety Standards or a route safety plan
			  ○ make traveller declarations at certain times
			  ○ not exhibit COVID-19 symptoms
			  ○ wear face coverings in certain places
			  ○ undergo COVID-19 screening
			  ○ be considered to be a low risk of having or transmitting COVID-19
			  ○ maintain physical distancing
			• Overseas based aircrew who do not comply with these requirements are subject to isolation and quarantine requirements

MINISTRY OF HEALTH
MANATŪ HAUORA

Briefing

COVID-19 Therapeutics Portfolio - funding to secure products for COVID-19 prevention and treatment

Date due to MO:	8 January 2022	**Action required by:**	9 January 2022
Security level:	IN-CONFIDENCE-COMMERCIAL	**Health Report number:**	HR20220065
To:	Rt Hon Jacinda Ardern, Prime Minister Hon Grant Robertson, Minister of Finance Hon Chris Hipkins, Minister for COVID-19 Response Hon Andrew Little, Minister of Health		
Cc	Hon Nanaia Mahuta, Minister of Foreign Affairs Hon Aupito William Sio, Minister for Pacific Peoples Hon Peeni Henare, Associate Minister of Health Hon Ayesha Verrall, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Director General of Health	s 9(2)(a)
Maree Roberts	Deputy Director General, System Strategy and Policy	s 9(2)(a)

Minister's office to complete:

Approved	Decline	Noted
Needs change	Seen	Overtaken by events
See Minister's Notes	Withdrawn	
Comment:		

COVID-19 Therapeutics Portfolio - funding to secure products for COVID-19 prevention and treatment

Security level:	IN-CONFIDENCE-COMMERCIAL	**Date:**	2 January 2022
To:	Rt Hon Jacinda Ardern, Prime Minister Hon Grant Robertson, Minister of Finance Hon Chris Hipkins, Minister for COVID-19 Response Hon Andrew Little, Minister of Health		
Cc	Hon Nanaia Mahuta, Minister of Foreign Affairs Hon Aupito William Sio, Minister for Pacific Peoples Hon Peeni Henare, Associate Minister of Health Hon Ayesha Verrall, Associate Minister of Health		

Purpose of report

1. This report seeks your approval to draw down funding from the 'Minimising the health impacts of COVID-19 – Tagged Operating Contingency'. A drawdown will support Pharmac to secure a portfolio of COVID-19 therapeutics to support the pandemic response and management of COVID-19.

Summary

2. The COVID-19 pandemic has driven high rates of hospitalisation around the world, and COVID-19 treatment strategies have evolved with that experience.

3. To support the pandemic response and reconnecting New Zealanders, Ministers have indicated that New Zealand should be a fast mover in accessing COVID-19 therapeutics and in building the systems to use them [HR20211968 refers].

4. On 17 November 2021, the Cabinet Economic Development Committee agreed to increase the "Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency" (the contingency) by $300 million to enable Pharmac to secure new COVID-19 treatments in 2021/22 and 2022/23 [DEV-21-MIN-0235 refers].

5. Cabinet also agreed that, in addition to the new funding for therapeutics set aside in the contingency, Pharmac could purchase therapeutics using funds allocated from the Covid-19 Response and Recovery Fund (CRRF) to ensure the continuity of supply of medicines and medical devices in response to global supply issues caused by COVID-19.

6. Pharmac is currently working to assess and secure eight COVID-19 treatments to support New Zealand's pandemic response. The intention is to progressively secure a portfolio of COVID-19 treatments that would cover prevention of disease and treat all severities of illness, in hospitals and community settings.

7. Pharmac expects that $139 million will be required in 2021/22 to fund these treatments, with $25 million contributed by Pharmac from funds provided from the CRRF and $114 million drawn down from the contingency.

8. I propose that a further $750,000 be drawn down over 2021/22 and 2022/23 to allow Pharmac to recruit additional staff with the requisite skills to undertake its work on securing access to COVID-19 treatments and ongoing contract management and implementation over the course of the pandemic.

9. Further drawdowns may be required before 30 June 2022 if more purchase agreements for COVID-19 treatments are reached, or to put in place funding for 2022/23 once further purchasing requirements are firmed up.

Recommendations

I recommend you:

a) **note** that Pharmac is taking a portfolio approach to securing COVID-19 therapeutics to mitigate the impacts of COVID-19 on at-risk persons and health services

b) **note** that on 17 November 2021, the Cabinet Economic Development Committee [DEV-21-MIN-0235 refers]:

   i. agreed that "Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency" be increased by $300 million to provide for the purchase of COVID-19 therapeutics in 2021/22 and 2022/23

   ii. noted that in July 2020, Pharmac received funding from the COVID-19 Response and Recovery Fund (CRRF) to ensure the continuity of supply of medicines and medical devices in response to global supply issues caused by COVID-19 [CAB-20-MIN-0328.25 refers]

   iii. agreed that in addition to the new funding for therapeutics set aside in the operating contingency above, that Pharmac can also use their existing funding noted in paragraph b) ii above for the purchase of COVID-19 therapeutics

   iv. noted that the Prime Minister, Minister of Finance, Minister for COVID-19 Response, and Minister of Health have authority to jointly approve the drawdown of funding from the above operating contingency

d) **note** that Pharmac:

   i. have funded or secured supply of four therapeutics (Ronapreve, Baricitinib, Remdesivir, and Tocilizumab);

ii. have secured advance purchase agreements (APAs) for two therapeutics (Molnupiravir and Paxlovid);

iii. have two therapeutics still under assessments (Sotrovimab and Evusheld)

e) **note** that Pharmac is able to contribute $25 million towards these purchases from funds provided from the CRRF for medicines costs related to COVID-19

f) **agree** to drawdown $114.750 million from the "Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency" for Pharmac to fund the remaining costs of securing a portfolio of COVID-19 therapeutics including additional operational funding for PHARMAC to support these purchases Yes/No

g) **approve** the following changes to appropriations to provide for the decision in recommendation f) above, with a corresponding impact on the operating balance and net core Crown debt: Yes/No

	$m – increase/(decrease)				
Vote Health **Minister for COVID-19 Response**	2021/22	2022/23	2023/24	2024/25	2025/26 & outyears
Multi-Category Expenses and Capital Expenditure: Implementing the COVID-19 Vaccine Strategy (MCA)					
Non-Departmental Output Expense: Purchasing Potential and Proven COVID-19 Vaccines and Other Therapeutics	114.000	-	-	-	-
Vote Health **Minister for Health**					
Non-Departmental Output Expenses: National Management of Pharmaceuticals	0.250	0.500	-	-	-
Total Operating	**114.250**	**0.500**	-	-	-
Total Capital	-	-	-	-	-

h) **agree** that the proposed changes to appropriations for 2021/22 above be included in the 2021/22 Supplementary Estimates and that, in the interim, the increases be met from Imprest Supply; Yes/No

i) **agree** that the expenses incurred under recommendation g) above be charged against the "Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency" Yes/No

j) **note** that, following the changes to appropriations detailed in recommendation g) above, the remaining balance of contingency funding provided for the

purchase of COVID-19 therapeutics under "Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency" will be $185.250 million

k) **note** that the "Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency" will expire on 1 February 2023

l) **note** that further drawdowns may be required before 30 June 2022 if other purchase agreements for COVID-19 treatments are reached.

Ashley Bloomfield
Te Tumu Whakarae mō te Hauora
Director-General of Health
8/2/22

Rt Hon Jacinda Ardern
Prime Minister
8/3/22

Hon Grant Robertson
Minister of Finance
...../...../.....

Received on 3/3/22

Hon Chris Hipkins
Minister for COVID-19 Response
...../...../.....

Hon Andrew Little
Minister of Health
...../...../.....

COVID-19 Therapeutics Portfolio - funding to secure products for COVID-19 prevention and treatment

Background / context

10. Under the COVID-19 Protection Framework, there is a focus on minimising the impacts of COVID-19 while it is in communities, to create certainty and sustainability. This includes minimising significant health impacts and the flow on effects of the pandemic on other health services.

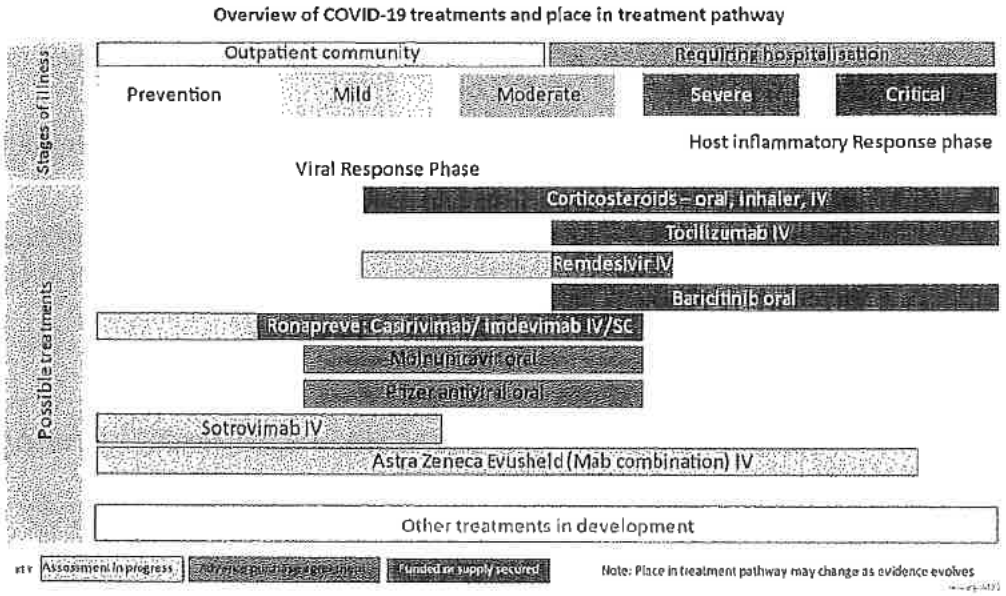
11. In the current highly vaccinated context, New Zealand's pandemic response is shifting towards managing some level of COVID-19 in communities. In this context, therapeutics will play a role in protecting at-risk individuals, preventing severe disease, and as well as treating severe illness in hospitals.

12. Pharmac is taking a portfolio approach to secure access to a range of COVID-19 treatments. This approach reflects the urgency, global demands on supply and the early stage of development for many treatments. Pharmac are assessing treatments and supply as soon as information is available, prior to Medsafe approval.

13. Pharmac is progressively securing a portfolio of therapeutics to prevent disease and treat all severities of illness in both hospitals and community settings (refer to Figure 1).

14. The approach considers emerging and evolving evidence on therapeutics and on the COVID-19 variants. Evidence is still emerging on effectiveness against the Omicron variant. Pharmac and Ministry of Health staff are liaising with other jurisdictions to learn from international experiences.

Figure 1: An overview of COVID-19 treatments being considered and their potential place in treatment pathway for patients with COVID-19.



15. In November 2021, Cabinet [DEV-21-MIN-0235 refers]:

    a. approved $300 million in contingency funding, for new potential or proven COVID-19 treatments, to secure advance purchase arrangements for treatments required in 2021/22 and 2022/23

    b. agreed, that in addition to the new funding for therapeutics set aside in the operating contingency above, the Pharmac can also use their existing funding [allocated from the CRRF to ensure the continuity of supply of medicines and medical devices in response to global supply issues caused by COVID-19] for the purchase of COVID-19 therapeutics, and

    c. noted that the Prime Minister, Minister of Finance, Minister for COVID-19 Response, and Minister of Health have authority to jointly approve the drawdown of funding from the "Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency".

Progress to date

Pharmac is currently working to assess and secure a portfolio of COVID-19 therapeutics

16. Pharmac has identified several suppliers with a range of treatments for COVID-19.

17. These products include new emerging products, and existing products repurposed for the treatment of COVID-19. Pharmac is currently working to assess and secure several COVID-19 treatments. As more information is available, the relative interest in and priorities for these products is likely to change. Details of all COVID-19 treatments currently being considered by Pharmac and Medsafe are included with this briefing (refer to Appendix 1).

18. Negotiations are proceeding in different phases. Key progress to date includes:

a. securing 12,800 treatment courses of Ronapreve through an APA with Roche – Ronapreve is now approved by Medsafe, listed on the Pharmaceutical Schedule and available for use

b. securing supply of 60,000 treatment courses of molnupiravir, Merck Sharpe and Dohme's antiviral treatment, through an advance purchase agreement, subject to Medsafe approval

c. securing 60,000 treatment courses of Pfizer's antiviral treatment, Paxlovid, through an APA, subject to Medsafe approval

d. securing stocks of baricitinib, an oral tablet alternative to tocilizumab (intravenous infusion), from Eli Lily – baricitinib is available for use where tocilizumab is in short supply.

Expected costs for COVID-19 treatments (contains confidential pricing)

Drawing down funding from the tagged contingency to allow Pharmac to purchase COVID-19

19. Current estimated expenditure for COVID-19 treatments in 2021/22 is approximately $139 million. Pharmac expects to be invoiced this amount by 30 June 2022, based on estimated timeframes for Medsafe approval and the earliest possible deliveries. The amount includes completed purchase arrangements and some unconfirmed purchases where negotiations are in progress.

20. Pricing for individual products is highly confidential with confidentiality agreements in place.

21. Pharmac expects to be able to contribute $25 million of funding allocated from the COVID-19 Response and Recovery Fund for COVID-19 medicines supply chain funding [DEV-21-MIN-0235 refers] towards these purchases.

22. A drawdown of the remaining $114 million from the "Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency" is sought as soon as possible to ensure access to these COVID-19 therapeutics.

23. Further drawdowns are likely required early in the 2022/23 financial year (prior to 30 June 2022) if other purchase agreements are reached and supply is available. Pharmac expect ongoing costs for 2022/23 to be confirmed in the coming months, however precise timing will depend on conclusion of APA negotiations with suppliers and approval of therapeutics by Medsafe.

Increase to Pharmac Operational Budget

24. Securing the delivery of COVID-19 treatments has involved significant additional work for Pharmac with no additional resource. COVID-19 therapeutics work includes complex negotiations with suppliers, fast decision making, the establishment and support of a new COVID-19 specialist advisory committee, and engagement with the Ministry of Health and external stakeholders on arrangements for the distribution of COVID-19 treatments. It has been made a priority over business-as-usual work programmes, with impacts on the latter including delays and hiatuses in projects.

25. Pharmac is seeking an increase of $750,000 to its operational budget for the remainder of 2021/22 ($250,000) and in 2022/23 ($500,000) through the drawdown from the "Minimising the Health Impacts of COVID-19 – Tagged Operating Contingency".

26. This would support Pharmac to recruit additional staff to undertake work securing access to COVID-19 treatments and ongoing contract management and implementation.

Equity

27. Access to therapeutics is likely to save lives, reduce health and wellbeing impacts of COVID-19, increase health system performance by reducing pressure on hospital services, and support New Zealand's cultural, social and economic recovery from COVID-19.

28. A portfolio of therapeutics applicable in a range of scenarios is likely to provide greater protection to people at high risk of the impacts of COVID-19 including Māori, Pacific peoples, disabled and older peoples, and people with multiple health conditions.

Next steps

29. Pharmac and the Ministry will continue to monitor emerging evidence on the effectiveness of treatments against the Omicron variant.

30. Pharmac is working with the Ministry and Medsafe on the approval, distribution, and delivery arrangements for COVID-19 therapeutics

31. Pharmac will continue to keep Vaccine Ministers informed weekly, on progress with Pharmac and Medsafe's work to secure supply of COVID-19 treatments, and the status of the portfolio of treatment products.

ENDS.

Appendix One: COVID-19 treatments status report

Appendix One: COVID-19 treatments status report (changes from last report underlined)

Pharmaceutical	Supplier	Medsafe approval status	Indication and/or evidence for use in COVID-19	Current status and availability in NZ (as at 19 January 2022)
Dexamethasone (oral tablets, intravenous)	Aspen/ Multichem	Approved for other indications Dexamethasone tablets were approved in November 2020 for treatment of COVID-19 in patients aged 12 years and older who require supplemental oxygen therapy	Moderate to severe cases	Already funded on the Pharmaceutical Schedule and supply levels above usual (more than six months). Pharmac continues to secure additional supplies for both formulations to support use in COVID-19 in addition to other uses.
Tocilizumab (intravenous infusion; subcutaneous injection)	Roche	Approved (and funded) in NZ for rheumatoid arthritis Indication for COVID-19 still to be submitted to Medsafe. Timing not yet confirmed. Tocilizumab is approved for the treatment of COVID-19 by the US FDA[1] and is under evaluation by the EMA[2]	Moderate to severe cases	From 1 October 2021, funded in NZ for treatment of hospitalised patients with moderate to severe COVID-19. Has been used to treat hospitalised patients in current outbreak. While supplies are still limited, new stock of the intravenous product was delivered in January 2022. Pharmac is working with DHBs and the supplier to manage this stock and continue to prioritise use for COVID-19. Supplies of an alternative subcutaneous injectable product, for use in COVID-19 and non-COVID-19 patients, is also available through DHB hospitals as a backup option.
Remdesivir (intravenous)	Gilead	Not approved in NZ Medsafe received an application in October 2021 for approval for the treatment of COVID-19 Currently approved in US, EU	Moderate to severe cases	Stock available in NZ for approximately 180 patients. Pharmac will consider changes to remdesivir criteria based on recently published evidence. Clinical advice was sought from Pharmac's COVID-19 Treatments Advisory Group in December 2021. Current stock is based in Auckland and Dunedin.

[1] FDA – Food and Drug Administration, United States of America
[2] EMA – European Medicines Agency

Pharmaceutical	Supplier	Medsafe approval status	Indication and/or evidence for use in COVID-19	Current status and availability in NZ (as at 19 January 2022)
		and Australia		Ongoing supply is being secured.
Baricitinib (oral tablets)	Eli Lilly	Registered in Australia for Rheumatoid arthritis Not approved in NZ and prescribers will need to comply with section 25 of the Medicines Act 1981 s 9(2)(b)(ii)	Moderate to severe cases (could be used as an alternative to tocilizumab) Will be restricted for use in hospitalised patients	In October 2021, Pharmac secured an initial supply of 500 treatment courses of baricitinib. Discussions with the supplier are ongoing to confirm long term supply arrangements. Stock has arrived in NZ and has been distributed to DHB hospital pharmacies. We expect further treatment courses to be available in early February 2022. Consultation on proposed access criteria was issued on 22 December 2021. Baricitinib will be available for those that meet the criteria from 1 February 2022. Pharmac expects to notify this decision soon.
Casirivimab/ imdevimab (Regen-COV/ Ronapreve) (subcutaneous injection and IV infusion) To be supplied as multidose vials	Roche	Approved by Medsafe December 2021	Proposed indications include: • treatment in patients over 12 years old that do not require supplemental oxygen and who are at high risk of progressing to severe COVID-19. • prevention of COVID-19 in individuals aged 12 years and older who have been exposed, or at high risk of exposure, or have a medical condition making them unlikely to be protected by vaccination.	Pharmac has secured 12,800 treatment courses of casirivimab/imdevimab (Ronapreve), through an advance purchase agreement. Consultation on proposed access criteria was issued on 22 December 2021. Ronapreve will be available for those that meet certain access criteria from 1 February 2022. Pharmac expects to notify this decision soon. Access prior to 1 February 2022 can be considered through Pharmac's Exceptions pathway. Casirivimab and imdevimab is not expected to be effective against the Omicron variant of COVID-19.

Pharmaceutical	Supplier	Medsafe approval status	Indication and/or evidence for use in COVID-19	Current status and availability in NZ (as at 19 January 2022)
Sotrovimab (infusion)	GSK	Supplier has not yet submitted an application to Medsafe	Prevention and treatment of mild cases	Discussions with supplier ongoing. GSK unable to consider supply and regulatory assessment to NZ at this stage, to be reconsidered by GSK in March 2022.
Antiviral (nirmatrelvir and ritonavir - Paxlovid) (oral)	Pfizer	Medsafe has received an application for Paxlovid. This application is being submitted by rolling application, to allow Pfizer to submit different sections of the dossier to Medsafe as soon as the date becomes available. Only limited data has been supplied to Medsafe to date https://www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp.	Proposed indications: • treatment of adult patients with symptomatic confirmed infection • post-exposure prophylaxis (eg close contacts)	Pharmac has agreed terms of the advance purchase agreement with Pfizer. Negotiation of the final agreement is in progress. We are working with the supplier to progress this as soon as possible. Indemnity clauses to be discussed with Treasury. We have committed to 60,000 treatment courses, subject to Medsafe approval. Clinical advice was sought from Pharmac's COVID-19 Treatments Advisory Group in December 2021. We plan to consult publicly on proposed access criteria later in January 2022. Delivery to New Zealand could occur as early as April 2022.
Molnupiravir (oral)	MSD	Not approved in NZ Medsafe is in correspondence with MSD regarding a potential new medicine application. Expected February 2022. MSD has received emergency use authorisation in the US	Proposed indications: • treatment of adult patients with symptomatic confirmed infection • post-exposure prophylaxis (eg close contacts)	Confidentiality agreement signed and key terms for advance purchase agreement signed. Negotiation of the final agreement is in progress. Indemnity clauses to be discussed with Treasury. Clinical advice was sought from Pharmac's COVID-19 Treatments Advisory Group in October 2021. We plan to consult publicly on proposed access criteria later in January 2022. First delivery to New Zealand could occur from April 2022, pending MSD submission to Medsafe and approval.

Pharmaceutical	Supplier	Medsafe approval status	Indication and/or evidence for use in COVID-19	Current status and availability in NZ (as at 19 January 2022)
s 9(2)(f)(iv)		Supplier has had initial conversation with Medsafe regarding regulatory approval Currently under assessment by regulatory authorities in the US, EU, Canada and Australia No indication of when an application will be sent to Medsafe	Confirmed cases that do not require supplemental oxygen and at high risk of progressing to severe disease	Pharmac discussing with supplier. Negotiations and clinical advice to be progressed. Product information, including clinical summaries, has been provided by s 9(2)(f) Clinical advice was sought from Pharmac's COVID-19 Treatments Advisory Group in December 2021.
		Not approved in NZ Phase III data, being considered for approval and/or emergency use in other jurisdictions No indication of when an application will be sent to Medsafe	Likely to be used in hospitalised patients	Pharmac met with s 9(2)(f)(iv) on 7 October 2021. Product information, including clinical summaries, has been provided by s 9(2)(f)(iv)
Tixagevimab and cilgavimab (Evusheld) (infusion)	Astra Zeneca	Not approved in NZ Under evaluation by European Medicines Agency No indication of when an application will be sent to Medsafe	Prevention of infection in people who are not infected Confirmed cases within a week of symptoms, to prevent severe infection and death Suitable for people who haven't responded to a vaccine	Pharmac has received an initial briefing from AstraZeneca. More information is being sought from AstraZeneca and a confidentiality agreement has been signed. Clinical advice was sought from Pharmac's COVID-19 Treatments Advisory Group in December 2021. Product could be available mid-2022.

Briefing

Proposed changes to managed isolation and quarantine settings in Phase Two and Phase Three of the Omicron response plan

Date due to MO:	10 February 2022	**Action required by:**	14 February 2022
Security level:	IN CONFIDENCE	**Health Report number:**	202220175
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Te Tumu Whakarae mō te Hauora Director-General of Health	s 9(2)(a)
Maree Roberts	Deputy Director-General, System Strategy and Policy	s 9(2)(a)

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

Proposed changes to managed isolation and quarantine settings in Phase Two and Phase Three of the Omicron response plan

Security level:	IN CONFIDENCE	**Date:**	10 February 2022
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Purpose of report

1. This briefing recommends that you:

   a. agree to make amendments to the COVID-19 Public Health Response (Isolation and Quarantine) Order 2020 (IQO) regarding the length of stay and testing frequency in managed isolation and quarantine (MIQ) to support Phase Two and initial stages of Phase Three of the Omicron response plan.

   b. consult on the proposals in this briefing with the Prime Minister, the Minister of Justice, the Minister of Health, and any other Ministers you think fit by Monday 14 February 2022.

   c. agree that subject to your consultation with your Ministerial colleagues, the Ministry of Business, Innovation and Employment's Managed Isolation and Quarantine team (MBIE MIQ) will issue drafting instructions to the Parliamentary Counsel Office (PCO) to draft the required IQO amendments to give effect to the proposals in this report.

Summary

2. To support a future shift to Phase Two and initial stages of Phase Three of the Omicron response plan several changes to the IQO have been identified, including

   a. reducing the length of stay in managed isolation from 10 days to 7 days

   b. removing the Day 3 test, and if we move to 7-day MIQ stay, also removing the Day 9 test and instead requiring a Day 0/1 and Day 5/6 PCR test

   c. reducing the length of quarantine from 14 days to 10 days for cases (from date of positive test) and their bubble contacts that remain in the same room as the case

   d. reducing the length of quarantine for other close contacts from 10 days to 7 days.

3. Most of these changes provide greater consistency between MIQ and the management of community close contacts and cases in Phase Two of the Omicron response plan.

4. Subject to your approval and following consultation with your Ministerial colleagues, the changes outlined in this briefing will be drafted into a single amendment to the COVID-

19 Public Health Response (Isolation and Quarantine) Order 2020 along with other changes MBIE-MIQ is seeking.

Recommendations

We recommend you:

a)	**Note** that to support a shift to Phase Two of the Omicron response plan the Ministry of Health has identified changes required to the COVID-19 Public Health Response (Isolation and Quarantine) Order 2020 regarding the length of stay and testing frequency in managed isolation and quarantine.	**Noted**
b)	**Agree** to the proposed changes to the COVID-19 Public Health Response (Isolation and Quarantine) Order 2020 set out in the tables in this briefing.	**Yes/No**
c)	**Note** that MBIE MIQ will be providing you with a separate briefing outlining the operational implications and amendments to the COVID-19 Public Health Response (Isolation and Quarantine) Order 2020 that will be necessary to give effect to the proposed changes [BR 21222661].	**Noted**
d)	**Agree** to consult on the proposal in this briefing with the Prime Minister, the Minister of Justice, the Minister of Health, and any other Ministers you think fit by Monday 14 February 2022.	**Yes/No**
e)	**Agree** that subject to the outcome of your consultation with your Ministerial colleagues, MBIE MIQ will issue drafting instructions to the Parliamentary Counsel Office to draft the relevant amendments to the COVID-19 Public Health Response (Isolation and Quarantine) Order 2020 giving effect to the proposals in this briefing.	**Yes/No**
f)	**Note** that, subject to your approval, MBIE MIQ have advised that the changes outlined in this briefing will be drafted into a single amendment to the COVID-19 Public Health Response (Isolation and Quarantine) Order 2020 along with other changes MBIE-MIQ is seeking.	**Noted**

Dr Ashley Bloomfield
Te Tumu Whakarae mō te Hauora
Director-General of Health
Date: 10 February 2022

Hon Chris Hipkins
Minister for COVID-19 Response
Date: 11/2/2022

Proposed changes to managed isolation and quarantine settings in Phase Two and Phase Three of the Omicron response plan

Background

5. To support a shift to Phase Two of the Omicron response plan, amendments are required to the COVID-19 Public Health Response (Isolation and Quarantine) Order 2020 (IQO) regarding the length of stay and testing frequency in MIQ.

6. The proposed changes are outlined in the tables below for your agreement. These have been developed with input from the Ministry of Health's (the Ministry) Office of the Director of Public Health, Testing, Border Operations and Managed Isolation and Quarantine teams, the National Investigation and Tracing Centre, and MBIE MIQ.

Context

7. These changes have been proposed with the following in mind:

   a. *Consistency with the New Zealand Bill of Rights Act 1990* - that the least restrictive measures available be adopted to minimise the spread of COVID-19 in the community.

   b. *Proportionate and justifiable response to public health risks* - that there will be similar and/or greater risk of infection in the community compared to the risk of arrivals. It is also anticipated that there will be a greater demand for community testing and a consequent need to review MIQ testing protocols, and where appropriate align testing requirements with community guidance such as for close contacts.

   c. *Aligned with data, evidence, and parallel work* – that settings are aligned with our latest insights on Omicron and proposed community settings under the plan.

Proposed changes to managed isolation settings

Length of stay in managed isolation

Current setting	Proposed changes	Recommendation	Minister's Decision
People must stay in managed isolation for 10 days.	Shift to a 7-day managed isolation model from Phase Two, and into the initial stages of Phase Three.	**Agree** to that the length of managed isolation should decrease from 10 days to 7 days.	**Yes** **No**
Rationale Ministry analysis of MIQ testing results identified that in recent months, Day 6 testing has captured nearly all (between 90- 100 percent) of active cases - noting high-profile exceptions.			

Based on Delta case data, it is estimated that allowing people out of MIQ earlier may lead to a small increased risk of community transmission from returnees with between 80-90 percent of active cases being identified by the Day 0/1 and 3 tests combined, with no or very few cases detected after Day 6.

While it is difficult to determine how applicable this is to an Omicron context, initial data analysis shows that most cases continue to be detected within the first three days after arrival, and at least 90 percent by Day 5/6 testing.

Under Phase Two of the Omicron response plan, while there is a small (as yet unquantifiable) risk of acute cases being detected following exit from MIQ. This will not significantly add to the domestic public health risk. Additionally, as case numbers internationally decline, the risk of this will also reduce.

8. The above change should be implemented as soon as practicable after the move to Phase Two. While the move to Phase Two removes the public health rationale for the quarantine and isolation periods (of 14 and 10 days respectively), their retention may still be necessary (from a New Zealand Bill of Rights Act 1990 perspective). This allows time to operationalise changes including, to update passenger arrival systems, process adjustments to regulatory settings, and/or to accommodate airlines and airport authorities.

9. The Ministry will work through the timing of any legislative and operational changes with MBIE MIQ. This recognises that MBIE MIQ need at least three working days lead-in time for implementation.

Testing requirements for people in managed isolation

Current setting	Proposed changes	Recommendation	Minister's Decision
PCR testing on Day 0/1, 3, 6, 9.	Remove the Day 3 test when we move to 7-day MIQ, the Day 9 test will no longer take place. Day 0/1 and Day 5/6 PCR test. PCR testing is retained.	**Agree** to remove the Day 3 test when we move to 7-day MIQ **Agree** to retain a Day 0/1 and Day 5/6 PCR test for people in managed isolation. **Agree** to retain PCR testing.	**Yes** / **No** **Yes** **No** **Yes** **No**

Rationale

Reducing the frequency of returnee testing and focusing on the Day 0/1 test (initial entry test with the greatest detection rate) and the Day 5/6 test (the final 'exit' test) will:

a. alleviate pressure on the MIQ health workforce.

b. reduce the pressure the MIQ system places on the lab system, which will free up lab capacity to support community testing.

c. align with the testing schedule of close contacts in the community under Phase Two of the Omicron response.

Retaining PCR testing for returnees in MIQFs at this stage (rather than moving to Rapid Antigen Testing) ensures greater reliability of results, which we consider to be appropriate under the 'high risk pathway'. Continuing to use PCR testing also provides the ability to undertake whole genome sequencing to identify new variants crossing the border.

Anyone who develops symptoms prior to release from MIQ will continue to be tested, regardless of day of stay.

Proposed changes to quarantine settings

Length of stay in quarantine

Current setting	Proposed changes	Recommendation	Minister's Decision
14 days and 72 hours symptom-free for cases. 10 days for close contacts.	10 days for cases (from date of positive test) AND their bubble contacts that remain in the same room as the case 7 days for any other close contacts.	**Agree** that the length of stay in quarantine for cases AND their bubble contacts that remain in the same room as the case should change from 14 days to 10 days (from date of positive test).	**Yes** / **No**
		Agree that the length of stay in quarantine for any other close contacts should change from 10 days to 7 days.	**Yes** / **No**

Rationale

This change provides consistency with the management of community close contacts and cases in Phase Two of the Omicron response plan.

The treatment of bubble contacts mirrors that of household contacts and who will be defined as a probable case at Phase Two.

For cases and probable cases, being 72-hours symptom-free will be a requirement as outlined in the draft section 70 notice currently being developed by Health Legal for Phase Two.

Testing requirements for people in quarantine facilities

Current setting	Proposed changes	Recommendation	Minister's Decision
Day 5 and 8 for close contacts.	Day 0/1 and 5 for close contacts and no testing for active cases.	**Agree** that testing occur on Day 0/1 and Day 5 for close	**Yes** **No**

No testing for active cases.		contacts and continue to not test active cases.	

Rationale

This change provides consistency with the management of community close contacts and cases in Phase Two of the Omicron response plan.

Testing modality

10. It is proposed to continue with the current PCR nasopharyngeal swabbing (NPS) testing modality initially when we transition to a 7 day MIQ stay, as it is a well-established process, and the health workforce are currently well equipped to deliver two NPS tests for each returnee. Retaining PCR testing at this stage will also ensure greater reliability of results. It also provides the ability to undertake whole genome sequencing to identify new variants crossing the border.

11. The Ministry is continuing to scope the use of alternative tests, including the use of self-administered PCR saliva testing for returnees. This would further alleviate pressure on the health workforce as it is self-administered – which will be particularly important if there are high levels of staff absenteeism during the community outbreak.

Remaining MIQ settings

12. At this stage, I recommend that all other MIQ settings remain the same as in Phase One of the Omicron response plan. The changes above are proposed with a focus on Phase Two but will likely remain relevant for the initial stages of an eventual shift to Phase Three. However, when that occurs, they will be reviewed again.

Equity

13. These proposals are part of maintaining effective border protection, to keep our communities safe and particularly those most at risk.

14. Those returning to New Zealand should not have to stay in MIQ any longer than is necessary to protect the public health of New Zealanders. Recent evidence indicates that the increased risk of transmission of COVID-19 from reducing a returnee's isolation period to 10 days is low, with the series of tests and other appropriate mitigations now in place. This is consistent with our proposed approach to the management of community close contacts.

15. Reducing the length of stay in MIQ will also reduce the cost for returnees making the system more affordable to a wider range of people.

s 9(2)(h)

[redacted]

s 9(2)(h)

[redacted]

Next steps

17. If you agree to the proposed changes to MIQ settings above following consultation with your Ministerial colleagues by Monday 14 February 2022, MBIE MIQ will include them in their drafting instructions to the Parliamentary Counsel Office to make the necessary amendments to the IQO.

18. Pending your agreement to these proposals, MBIE MIQ will require three working days to implement these changes once the date for the shift to Phase Two of the Omicron response plan is confirmed. MBIE MIQ will also provide you with a separate briefing on this matter [BR 21222661 refers].

ENDS.

MINISTRY OF HEALTH
MANATŪ HAUORA

Briefing

Further advice on expanding the influenza immunisation programme for 2022 in response to COVID-19

Date due to MO:	18 February 2022	**Action required by:**	18 February 2022
Security level:	IN CONFIDENCE	**Health Report number:**	20220038
To:	Rt Hon Jacinda Ardern, Prime Minister Hon Grant Robertson, Minister of Finance Hon Chris Hipkins, Minister for COVID-19 Response Hon Andrew Little, Minister of Health Hon Dr Ayesha Verrall, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Te Tumu-Whakarae mō te Hauora Director-General of Health	S9(2)(a)
Astrid Koornneef	Director, National Immunisation Programme	S9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Further advice on expanding the influenza immunisation programme for 2022 in response to COVID-19

Security level:	IN CONFIDENCE	**Date:**	18 February 2022

To: Rt Hon Jacinda Ardern, Prime Minister
Hon Grant Robertson, Minister of Finance
Hon Chris Hipkins, Minister for COVID-19 Response
Hon Andrew Little, Minister of Health
Hon Dr Ayesha Verrall, Associate Minister of Health

Purpose of report

1. To provide further advice to inform the decision to expand the influenza immunisation programme for 2022 [SWC-21-MIN-0223].

Summary

2. With the borders closed due to the COVID-19 pandemic, New Zealand has had no to very low influenza infections for the past two years. This reduction in infections is likely to have led to lower-than-normal immunity against the virus in the New Zealand population.

3. The presence of both influenza and COVID –19 (particularly Omicron) circulating in the community presents with an extraordinary situation where the risk of co-infection and the impact on an already stretched health system is high. In December 2021, Cabinet agreed in principle (subject to this advice) to expand the 2022 influenza immunisation programme and directed the Ministry of Health (the Ministry) to work with Pharmac to provide this advice to Vaccine Ministers [SWC-21-MIN-0223].

4. This advice provides further information, costs and an implementation plan to include a whānau-based approach (Option 1) for the 2022 influenza immunisation programme.

5. Subject to this advice, Cabinet has authorised the Prime Minister, Minister of Finance, Minister for COVID-19 Response and the Minister of Health to jointly approve the drawdown of funding required for 2022 influenza immunisation programme from the COVID-19 Response and Recovery Fund (CRRF).

Recommendations

We recommend you:

		Prime Minister	Minister of Finance	Minister for COVID-19 Response	Minister of Health	Associate Minister of Health
a)	**Note** that there is a risk with the borders reopening that the 2022 influenza season may have a greater impact on New Zealanders and on an already stretched health system.					
b)	**Note** Cabinet agreed, in principle, to extending the 2022 influenza immunisation programme given the high public health risk in anticipation of borders reopening [SWC-21-MIN-0223]					
c)	**Note** that Cabinet has made a decision to reopen borders in a staged approach with first stage taking place on 11:59pm on Sunday 27 February 2022 [CAB-22-MIN-0008]					
d)	**Note** that currently publicly funded influenza vaccination is targeted at people at highest risk of serious illness, namely, people aged 65 years and over, pregnant people, those with certain chronic or serious conditions and young children (under four years old) with a history of serious respiratory illness					
e)	**Note** that this advice presents two options for consideration: a. Option 1 – Whānau-based approach (Ministry recommended option) b. Option 2 – Age-based approach (extend current eligibility to include Māori and Pacific peoples (aged 55 to 64 years old) and children (aged 6 months to 5 years))					
f)	**Agree** to Option 1 for a whānau-based approach to the 2022 influenza immunisation programme OR	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**
g)	**Agree** to Option 2 for a age-based approach to the 2022 influenza immunisation programme	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**
FINANCIAL RECOMMENDATIONS:						
h)	**Approve** the drawdown of s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j) in funding, including s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j) in 2021/22 and s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j) in 2022/23, from the COVID-19 Response and Recovery Fund for costs related to extending the 2022 programme	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**	

	Prime Minister	Minister of Finance	Minister for COVID-19 Response	Minister of Health	Associate Minister of Health
i) **Approve** the following changes to appropriations to give effect to your decision in recommendation f) of g) above, with a corresponding impact on the operating balance and/or net core Crown debt		Yes/No		Yes/No	

Vote Health	**$ millions – increase / (decrease)**				
Minister of Health	**2021/22**	**2022/23**	**2023/24**	**2024/25**	**2025/26 & outyears**
Departmental Output Expense: Managing the Purchase of Services (funded by Revenue Crown)	2.250	1.250			
Non-Departmental Output Expense: Public Health Service Purchasing	S9(2)(b)(ii), S9(2)(ba)(ii), S9(2)(j)				
Total Operating			-		-

j) **Agree** that the expenditure in recommendation h) above be charged against the COVID-19 Response and Recovery Fund	Yes/No	Yes/No	Yes/No	Yes/No	
k) **Agree** that the above changes to appropriations for 2021/22 be included in the 2021/22 Supplementary Estimates and that, in the interim, the increase be met from Imprest Supply		Yes/No		Yes/No	
l) **Note** that the funding profile in recommendation i) above is based on the current estimate of when the costs will incur and dependent on the uptake of individual vaccine doses, there might be a need to seek in-principle transfers of some operating expenditure from 2021/22 to 2022/23 through Vote Health's June in-principle transfer process.					

Rt Hon Jacinda Ardern

Prime Minister

...../...../.....

Hon Grant Robertson

Minister of Finance

...../...../.....

Hon Chris Hipkins

Minister for COVID-19 Response

...../...../.....

Hon Andrew Little

Minister of Health

...../...../.....

Hon Dr Ayesha Verrall

Associate Minister of Health

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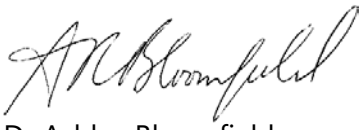

Dr Ashley Bloomfield

Director General of Health
Ministry of Health

18/02/2022

Astrid Koornneef

Director, National Immunisation Programme

Ministry of Health

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Further advice on expanding the influenza immunisation programme for 2022 in response to COVID-19

Background

6. Cabinet has agreed that our borders will reopen with the first step to take place at 11:59pm 27 February 2022 [CAB-22-MIN-0008]. Since the closure of the borders due to COVID-19, New Zealand has had low influenza infections (if any). This situation will change when borders reopen and Managed Isolation and Quarantine facilities removed for all arrivals leading to an increased importation of infectious diseases, such as influenza.

7. Cabinet also agreed, in principle subject to this advice, to extend the eligibility of publicly funded groups for 2022 programme as part of New Zealand's overall response to COVID-19. The COVID-19 Vaccination Technical Advisory Group (CV TAG) advised to help mitigate risks for New Zealanders from influenza during the COVID-19 pandemic, was by providing for greater access to free influenza vaccine to combat the high public health risk influenza poses.

8. The focus of the 2022 influenza immunisation programme (2022 programme) starting on 1 April 2022 will be to maximise uptake of the vaccine with a focus on protecting our high-risk populations and their whānau, in order to reduce the burden of influenza and the impact on the health system.

9. This advice provides analysis on demand (estimate), financial implications and an outline of the implementation approach to support a whānau-based approach from 1 April 2022.

Analysis

We are in an extraordinary situation with the COVID-19 pandemic and as we prepare to reconnect to the world, we can expect to see more seasonal influenza in New Zealand

10. The reduction in influenza infections over the past two years is likely to have led to lower-than-normal immunity against the virus in the New Zealand population. The presence of both influenza and COVID-19 (particularly Omicron) circulating in the community presents an extraordinary situation where the risk of co-infection and impact on an already stretched health system is high.

11. Concomitant administration is available for most immunisations (except Zostavax) alongside the COVID-19 vaccine. However, by bringing forward the booster dose interval to three months for the majority of the eligible population, it now provides an opportunity for the workforce to have more capacity to deliver other immunisations, such as the influenza vaccine.

12. The World Health Organization (WHO) has recommended countries to increase surveillance of influenza during the COVID-19 pandemic to and stepping up influenza vaccination campaigns to prevent severe disease and hospitalisation associated with influenza and

prepare for co-circulation of influenza and COVID-19.[1] The impact of co-infection of influenza and COVID-19 is still unknown. Cases of co-infection are being detected in countries including the United States, Israel, Brazil, the Philippines and Hungary.[2]

The same groups who are at higher risk of COVID-19 are also at higher risk of severe outcomes following influenza infection

13. Those who are at greatest risk from influenza infection are eligible for a publicly funded influenza vaccination. This is particularly important for Māori and Pacific populations who have greater need (higher rates of pre-existing conditions) and routinely lower rates of influenza vaccinations across all age groups.

14. The COVID-19 Vaccination Technical Advisory Group (CV TAG) advised that to help mitigate risks for New Zealanders from influenza during the COVID-19 pandemic, greater access to free influenza vaccine should be provided to combat the high public health risk from influenza.

More needs to be done to maximise uptake and this can be achieved through careful planning and utilising our experience and infrastructure from the successful COVID-19 Vaccine and Immunisation Programme

15. We know we have not previously reached all of the eligible population for influenza vaccines, but through insights and learnings from our COVID-19 response, we now have the operational systems and structures in place to increase access and uptake.

16. The National Immunisation Programme has been preparing for the 2022 programme through an enhanced implementation approach that will focus on maximising uptake with the high-risk population groups as well adopting the whānau-based approach as utilised in our COVID-19 response.

17. Adopting a whānau-based approach for influenza that is culturally grounded, holistic and focused on improving wellbeing will be the priority.

Equity initiatives to resource Māori and Pacific Providers

18. While Government considers expanding the 2022 programme, outreach programmes such as the Māori Influenza and Measles Vaccination Programme (MIMVP) (which will in 2022 be expanded to Pacific providers) will be supported with additional funding to support the whānau-based approach.

19. The Ministry is working to build on the positive outcomes of the MIMVP. In 2022, the Ministry will position for future system settings to:

    a. expand the number of providers that can provide immunisation services

    b. integrate concomitant administration of Measles Mumps Rubella (MMR), influenza, COVID-19 (booster), HPV and childhood immunisation programmes, as appropriate

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[1] Influenza Update N° 411 (24 January 2022) at https://www.who.int/teams/global-influenza-programme/surveillance-and-monitoring/influenza-updates/current-influenza-update

[2] "*What is 'flurona'? Coronavirus and influenza co-infections reported as omicron surges*" (5 January 2022) at: https://www.washingtonpost.com/health/2022/01/05/flurona-coronavirus-flu-symptoms/

c. support Māori and Pacific designed services, increasing their capacity including workforce and reach

d. value services that provide holistic models of care based on relationships and improve access to immunisation services for both Māori and Pacific communities in New Zealand.

There are a range of options to increase equitable access and uptake of the influenza vaccine during this extraordinary year

20. The Ministry has analysed various options together with Pharmac and presents the following two options for consideration. These options are:

a. Option 1 – Whānau-based approach (Ministry recommended option)

b. Option 2 – Age-based approach (extend current eligibility to include Māori and Pacific peoples (aged 55 to 64 years old) and children (aged 6 months to 5 years))

Option 1 – Whānau-based approach (Ministry recommended option)

21. The whānau-based approach will apply to those currently eligible for a publicly funded influenza vaccination. Their whānau will also be eligible for a publicly funded influenza vaccination, irrespective of where they live and their age.

22. Insights from MIMVP shows that vaccination rates, particularly for Māori, increased when providers are enabled to take a whānau-based approach (i.e. those who are eligible bring whānau members with them to the vaccination site, and they can be offered a vaccine as well). Evidence indicates that vaccination rates for Māori over the age of 65 years increased from 45.8 percent in 2019 to 59 percent in 2020. The equity gap was reduced to negative 8.4 percent from negative 12.1%.

23. A whānau-based approach has also been successfully implemented through the COVID-19 Vaccine and Immunisation programme (CVIP). Providers are already able to target whānau and identify who would be eligible for publicly funded influenza vaccinations. Equitable access and uptake would be improved through a whānau-based approach while at the same time minimising the burden on the health system.

24. We recommend that a whānau-based approach be supported with two million vaccines. Pharmac are likely to secure an additional 220,000 doses, including 20,000 paediatric doses. Including alternative vaccines being supplied to the private market only, the total number of vaccines available if deals are finalised will be two million. The additional costs of these vaccines will need to be underwritten (see Financial implications).

Option 2 – Age-based approach (extend current eligibility to include Māori and Pacific peoples (aged 55 to 64 years old) and children (aged 6 months to 5 years))

25. CV TAG recommended that specific consideration be given to promoting and improving vaccine access to groups that have experienced disproportionate influenza morbidity and mortality, as well as those with barriers to routine health care, especially for Māori and Pacific peoples. This option uses an age-based approach (outside those already eligible) by lowering the age group for Māori and Pacific peoples and including children under the age of 5 years. This could potentially remove some of the barriers and reduce the higher health risks associated.

26. In 2018, Pharmac's Immunisation Subcommittee (the "Subcommittee") considered the proposal to expand eligibility to Māori and Pacific peoples aged from 55 to 64 years old for inclusion for publicly funded influenza vaccine. It observed that Māori and Pacific populations in this age group experienced higher morbidity and mortality from influenza.[3]

27. Immunising all children has the benefit of protecting them as individuals as well as reducing influenza transmission across the entire population. Māori and Pacific peoples, particularly children, live in multigenerational families and often in overcrowded conditions. They are at higher risk to influenza and COVID-19 infection and likely to transmit more easily into the community.

28. Using an age-based approach poses some risks that we need to balance in our implementation to ensure we do not detract from a focus on continuing to improve uptake of childhood immunisation such as MMR uptake, particularly for Māori and Pacific children.

There are some key issues that will still need to be worked through as we aim to maximise uptake and deliver influenza vaccinations more equitably

29. There are some key issues and risks which have been identified by Pharmac and the Ministry is working to manage these. Pharmac's concerns are primarily around how proposed changes would fit into current practices.

Proposed planning to source additional doses of influenza vaccines

30. Securing more doses is led by Pharmac as the procurer of the vaccine and there is a risk to supply as there is no guarantee of additional stock. For 2022, two million doses have been secured with Seqirus (contracted supplier) and 1.7 million doses is to supply the public and private market.

31. Seqirus have now provided an option to supply an additional 200,000 doses, underwritten by the Ministry of Health, for an expanded influenza immunisation programme. Pharmac will also seek an additional 20,000 paediatric formulation doses from Seqirus, who have first right of refusal under their sole-supply contract. This paper is seeking additional funding related to this total 220,000 doses from Seqirus.

32. This will be supported by 65,000 doses supplied by Sanofi and s9(2)(b)(ii) and s9(2)(ba)(ii) Fluad Quad doses by Seqirus to the private market, which while not financially secured, will bolster the overall number of vaccines available. The Sanofi vaccines can also be used to vaccinate children and provide a backstop should more vaccines be needed. There are also more Sanofi vaccines in Australia, which if New Zealand faces a short-supply situation, could be shipped to New Zealand.

33. Should we not be able to source sufficient supply of vaccines (paediatric or adult) as a result of supply constraints or unexpected high demand, equity should be prioritised for all patients eligible for a funded vaccination.

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[3] Paragraph 4.25 - Immunisation Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) Meeting held on 16 May 2018 at: https://pharmac.govt.nz/assets/ptac-immunisation-subcommittee-minutes-2018-6.pdf

34. Pharmac is currently in discussions with suppliers to finalise further supply options. The Ministry is confident that this quantity of vaccines, approximately 1.98 million doses, will be sufficient.

Financial implications

35. Cabinet authorised the Prime Minister, Minister of Finance, Minister for COVID-19 Response and the Minister of Health to approve and draw down from the tagged contingency for the programme subject to approval of this advice [SWC-21-MIN-0223].

36. The 2022 programme has already allocated funding to deliver education and training as well as a communication campaign and supporting collateral. Additional funding will be required to deliver a whānau based 2022 programme.

37. In addition to costs for supply of additional doses, funding is also sought to strengthen communications to increase awareness of the programme with a focus on Māori and Pacific communication channels.

38. Funding for the Māori Influenza and Measles Vaccination Programme (MIMVP) ran in 2020 (at a cost of $9.5 million) and in 2021 (at a cost $7.8 million) and has made a valuable contribution to Māori influenza vaccination rates. In an ordinary year, approximately $10 million[4] would have been sought for 2022. However, in 2022 we are expanding this programme to include Pacific Providers and with an enhanced influenza immunisation programme there is a need for more funding than before.

39. Supply of additional doses of influenza vaccines for either option will be the same, noting that forecasting exact demand would be difficult (see Appendix 2) and our approach is to have high supply to achieve uptake which exceeds those achieved in prior years to accommodate any increased demand stimulated.

40. Table 2 provides a breakdown of the funding required for either options proposed in this advice.

[4] The 2022 programme cost breakdown of $10 million is based on approximately $300,000 per Provider (average spend from the 2021 programme) + evaluation costs ($300,000) + Communications ($100,000).

Table 2: Breakdown of funding required

Cost breakdown based on activity area	Funding required for either option
Expanded 2022 Influenza immunisation programme (non-departmental expenditure)	
Approximate number of additional doses	220,000
Vaccine cost s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)	s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)
Administration costs ($23.20 per dose)	$5.104 million
Provider On-boarding (i.e. training, resources, tools etc)	$1.500 million
Subtotal for supply of additional doses	s9(2)(b)(ii), s9(2)(ba)(ii)
Additional funding for implementation sought (departmental expenditure)	
Promotion and communications campaign (i.e. media, promotional material etc.)	$3.000 million
National Immunisation Programme support	$0.500 million
Sub-total for implementation	**$3.500 million**
Additional funding required to support equity for the 2022 Māori and Pacific Outreach Immunisation Programme and other providers (non-departmental expenditure)	
2022 Māori and Pacific Outreach Immunisation Programme (enhanced)	$30.000 million
New Funding Required	s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)

41. Subject to your agreement, we seek approval from delegated Ministers (Prime Minister, Minister of Finance, Minister for COVID-19 Response and the Minister of Health) to jointly approve drawdown of s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j) across two financial years s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j) in 2021/22 and s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j) in 2022/23) from the COVID-19 Response and Recovery Fund to cover the anticipated costs of the expanded influenza vaccination programme in 2022 and to secure additional doses of the influenza vaccine, to be appropriated as shown in Table 3.

Table 3: Appropriations to fund Option1

Vote Health Minister of Health	$ millions – increase / (decrease)				
	2021/22	2022/23	2023/24	2024/25	2025/26 & outyears
Departmental Output Expense: Managing the Purchase of Services (funded by Revenue Crown)	2.250	1.250			

Non-Departmental Output Expense: Public Health Service Purchasing	s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)				
Total Operating	s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)	-		-	

42. Because the influenza immunisation programme runs from 1 April to 31 December 2022, we expect some of the costs will incur in 2022/23 and the current funding profile reflects our best estimate. Dependent on the actual uptake of individual vaccine doses [might be a need to seek in-principle expense transfers of some operating expenditure from 2021/22 to 2022/23 as part of Vote Health's June In-principle transfer process.

Implementation

43. Implementation of the 2022 programme will focus on improving coverage for those already eligible, expanded eligibility and high-risk population groups.

44. The Ministry will take an active role to deliver an enhanced implementation plan and leverage off communications, analytics, and other delivery and operational functions, learnings from the COVID-19 Vaccine and Immunisation Programme.

45. The Ministry is mindful of vaccine fatigue and will be thoughtful of this for the Influenza campaign.

46. Refer to Appendix 2 for an overview of the key enhancements of the implementation plan for the 2022 programme.

Equity

47. Improving access to influenza immunisation to all New Zealanders by removing barriers is likely to have a direct and noticeable impact and reduce the equity gap. The proposals in this paper will provide greater protection for population groups at high risk, particularly Māori, Pacific peoples, disabled peoples, pregnant peoples and children.

48. There is a significant equity gap between coverage for Māori and Pacific peoples, and coverage for non-Māori, non-Pacific. Any supply constraints due to high demand will then focus on equity as a priority for Māori and Pacific peoples. Māori and Pacific peoples need to be prioritised based on increased vulnerability to infection, being more likely to be part of the essential workforce and living in multigenerational households. Doing more of the same would not be effective in eliminating inequities. Eliminating barriers, alongside targeted implementation, will improve vaccine uptake and be a step to directly address health inequities experienced (particularly with coverage among children).

49. Older people living in long-stay residential care homes or other long-stay care facilities are also more at risk where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality.

50. Disabled people are vulnerable to complications from influenza. Equitable access remains important for disabled people. Expanding access for the 2022 Influenza immunisation programme will better provide coverage also for disabled people as well.

51. Immunisation for pregnant people and children provide the best protection against common infectious diseases such as influenza. Maternal immunisation provides additional protection for infants who cannot be directly vaccinated. Immunisation of healthy children has the potential to reduce illnesses and related costs in both children and their families.

Te Tiriti o Waitangi implications

52. There continues to be a focus on increasing vaccination uptake for Māori. In the past, and particularly throughout the COVID-19 response, iwi, hapū and whānau have exercised, and in many cases exceeded, good practice in line with government guidelines to maintain the wellbeing of their own whānau.

53. Increasing eligibility would better enable the Ministry to better respond to obligations under Te Tiriti in particular active protection and equity and would support other immunisation programmes where Māori vaccination rates are inequitable.

54. The proposals in this paper support health system resilience and maintain community protection. This is critical to minimising and addressing existing inequities and is consistent with Te Tiriti principle of active protection.

Next steps

55. Should Vaccine Ministers agree to our approach for the 2022 influenza immunisation programme and jointly approve the drawdown of funding, the Ministry will proceed to plan for the 2022 Influenza immunisation programme as contained in this advice, including confirmation of funding for providers, as appropriate.

ENDS

APPENDIX 1 – Modelling demand for 2022

- Assumptions have been made based on the implementation plan outlined in this advice including:
  a. Omicron variant could heighten public interest in vaccination in 2022 than in any previous year leading to an expectation of an extraordinary year for influenza.
  b. New Zealanders[5] are more aware of the effectiveness of immunisations and with global experience of COVID-19 (and Omicron) and the northern hemisphere influenza season.

Option 1 – Whānau-based approach (Ministry recommended option)

- To deliver a whanau-based approach, it is suggested to increase our total vaccine supply to two million doses. This will be covered by:
  - 1.7 million doses already committed by Seqirus
  - Additional 220,000 doses currently under negotiation, including 20,000 paediatric
  - s9(2)(b)(ii) and s9(2)(ba)(ii) doses of Fluad Quad supplied to the private market by Seqirus
  - 65,000 doses supplied to the private market by Sanofi
- Forecasting exact demand through this approach using population numbers (as with Option 2) is difficult. Therefore the recommendation is to ensure supply is high and notably exceeding uptake achieved in prior years to accommodate any increased demand stimulated through this approach.
- In addition, 2 million doses is likely to be achievable through negotiation with Seqirus

Option 2 – Age-based approach (extend current eligibility to include Māori and Pacific peoples (aged 55 to 64 years old) and children (aged 6 months to 5 years))

- We advise that 70 percent uptake in among the given base populations to most likely be achievable. However, we have also provided an estimate should uptake reach 90 percent in the eligible population, which we consider to be highly ambitious.
- Base populations for each group have been determined differently following cross-agency discussions on the best way to model forecasting. Forecasting for children is particularly difficult given the historically low uptake in this population.

[5] 94 percent (at 1 February 2022) of eligible New Zealanders are now vaccinated against COVID-19 indicating a clear sentiment of people being open to being vaccinated when they see the need for it.

- The table below shows dose requirements under varying levels of uptake:

	HSU Population	**HSU Population minus LTC**	**Additional doses needed for uptake**	
Maori and Pacific Aged 55-64	98,237	30,432	70 %	21,302
			80 %	24,346
			90 %	27,389
	Children aged under 5 vaccinated in a 3-month period		**Additional doses needed for uptake**	
Children aged 6 months to 5 years	85,000		70 %	59,500
			80 %	68,000
			90 %	76,500

Appendix 2 – Overview of the enhanced implementation plan

Implementation plan	
Stakeholder engagement	• A communications plan is being developed and external stakeholders have been identified. • The National Immunisation Programme is planning to meet with stakeholders in mid-February and then on a regular basis thereafter. • Engagement with Haurora Māori providers and Pacific Providers will commence mid-February and will be led by the Equity team. • New providers and vaccinators (i.e., Hauora Māori providers and Vaccinating Health Workers) will be enabled to deliver influenza immunisation, building on their success delivering COVID-19 vaccines providing provide new options for where and how people get immunised against influenza.
Communication and Promotional campaign	• Changes to the communications campaign in 2022 will be required in order to increase uptake of those currently eligible, include the expanded eligibility and achieve equitable immunisation coverage by targeting groups with lower vaccination rates such as Māori and Pacific peoples. • The current *Treasure our Whānau* campaign will be adapted to ensure promotion reaches all those eligible for a funded vaccine. Additional collateral has already been commissioned, to broaden promotional material to Pacific peoples and hapū māmā. • The influenza immunisation campaign should be driven through the tried and tested COVID-19 campaign channels and should adapt the *Treasure our Whānau* branding into the COVID-19 branding. This will strengthen the messaging by using well recognised branding and will ensure the public takes notice. • Messaging around concomitant delivery of the COVID-19 and influenza vaccines will be included so that the public and the sector are aware that it is safe to have them at the same time, rather than having to prioritise COVID-19 as happened last year, leading to low influenza vaccine uptake. • Consistent communications campaign will be created with coordinated and aligned messages for planned and reactive communications so that the health sector and the public receive the same information. • Continue to operate in a transparent, collaborative and constructive way with the public and sector stakeholders. • Outreach services that target Māori and Pacific peoples can be boosted in 2022 to increase uptake in these populations. With wider coverage

Implementation plan	
	of eligible groups for publicly funded vaccinations, Providers are then able utilise whānau-based approaches. • This campaign will continue to focus on improving uptake in people at high risk of serious illness and groups with historically low uptake, such as Māori and Pacific peoples.
Concomitant administration	• There is the opportunity concomitant administration of the influenza vaccination and COVID-19 vaccination, and other immunisations, where appropriate. This will be communicated with the sector. • MMR catch up vaccinations are now being offered alongside a number of COVID-19 vaccination providers. This approach will also have flow on effects to childhood immunisations. Where children, or their parents, present for an influenza vaccination, providers can offer or have a conversation about other childhood immunisations. This will help to opportunistically identify children who are behind on their childhood immunisations.
Workforce	• The programme will largely be delivered using the traditional workforce model (i.e. general practitioners, nurses and pharmacists) for publicly funded influenza vaccinations. • This model will be boosted by new providers and vaccinators (i.e. such as Hauora Māori providers and Vaccinating Health Workers). • This will provide other options for where people will get immunised against influenza. • Vaccinators who have been trained to administer COVID-19 vaccination will also be able to administer influenza, significantly boosting our vaccinator workforce. Note: Occupational Health Providers predominantly vaccinate in the private market. • General Practice will have the opportunity to record influenza vaccinations in the National Immunisation Solution (NIS) as well as their Practice Management Systems (PMS). • If a General Practice chooses to only use their PMS, then the Ministry will be able to obtain the influenza vaccine data for non-identifiable aggregate reporting. • General Practice and Pharmacy will continue to utilise their existing payment systems as the NIS is not linked to payments.
Service Delivery	• The influenza vaccination will be able to be administered in a range of setting: general practice, pharmacies, maraes, community vaccination centres. • Vaccine storage and distribution systems have been strengthened and the vaccinator workforce has been greatly expanded.

Implementation plan	
Infrastructure	• From 1 April 2022, all (publicly and privately funded influenza vaccinations) will be able to be recorded via a specific "form" in the National Immunisation Solution (NIS), which is the replacement for the National Immunisation Register. This is the first phase of the development of the NIS. • There is currently no legislative requirement for influenza vaccinations that are privately funded and privately provided to be entered into any national registry. Private providers would be encouraged to record influenza vaccinations in the NIS, but this may require some incentives such as funding or otherwise to support this.
Education, Training and Resources	• Tools and resources will be developed and available for providers to be used to used promote and deliver influenza immunisation programme effectively and safely. • Education and training will be available for those who will record influenza vaccination information into the NIS.
Quality, data and performance	• The Ministry will monitor the 2022 influenza immunisation programme performance. • Data requirements for reporting are being developed. This will enable a data driven approach to drive and enhance performance as experienced with the COVID -19 vaccination programme.

Briefing

Requiring COVID-19 vaccine booster doses to maintain vaccination status in the New Zealand context

Date due to MO:	17 February 2022	**Action required by:**	18 February 2022
Security level:	IN CONFIDENCE	**Health Report number:**	**20220254**
To:	Vaccine Ministers		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General, System Strategy and Policy	s 9(2)(a)
Wendy Illingworth	General Manager, Public Health System Policy, System Strategy and Policy	s 9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Requiring COVID-19 vaccine booster doses to maintain vaccination status in the New Zealand context

Security level:	IN CONFIDENCE	**Date:**	17 February 2022
To:	Vaccine Ministers		

Purpose of report

1. Following a request from Vaccine Ministers for further information, this paper provides advice on the implications of requiring a COVID-19 vaccine booster dose to maintain an up-to-date vaccination status. It does not seek a broad decision but sets out the practical and inter-related implications of any decision for Ministers to consider.

Summary

2. In November 2021 Cabinet agreed to commence the rollout of the booster programme, for people 18 years of age and over (CAB-21-MIN-0475 refers). Cabinet requested further information be provided to Vaccine Ministers on the implications of the COVID-19 booster programme for:
    a. the definition of 'fully vaccinated' (maintaining vaccination status)
    b. vaccine passes, and
    c. the COVID-19 Response (Vaccinations) Order 2022 (Vaccination Order).
3. When Vaccine Ministers met in late January 2022, discussion was held regarding when it would be reasonable and practical to include COVID-19 vaccine booster doses (boosters) in the "definition of fully vaccinated". This paper provides the further information that was sought at that time and sets out the implications of any future decision for Ministers to consider.
4. This paper discusses the broad public health aims of requiring boosters as well as the practical implications that would flow from any future decision. These include implications for vaccine passes, international arrivals, Vaccination Orders, international travel certificates and vaccine supply.
5. It includes up to date advice from the COVID-19 Vaccination Technical Advisory Group (CV TAG) on whether there is scientific evidence to support a decision to require boosters in further vaccination requirements. CV TAG has expressed the view any extension of the requirement for a booster dose beyond those already covered by Vaccination Orders would require a change to the intent of requirements (away from reduction of transmission) in order to be justified.
6. It also sets out options for My Vaccine Pass implementation, should boosters be required, and considers options for international arrivals and people on alternate vaccine pathways.
7. The Department of Prime Minister and Cabinet (DPMC) is currently undertaking a review of the use of My Vaccine Passes (MVP) the details of which the Minister for COVID-19 Response

will report back to Cabinet on in early March 2022. The outcome of the review will support any decision to include boosters in further vaccination requirements, and the Ministry will provide advice immediately following the report back on the review, to help support that decision.

Recommendations

We recommend you:

a) **Note** that in November 2021 Cabinet agreed to commence the rollout of the COVID-19 booster programme and requested further information be provided to Vaccine Ministers on the implications of the programme on the definition of "fully vaccinated", vaccine passes and Vaccination Orders. Following this in late January 2022, Vaccine Ministers requested further information to support considerations of including boosters in vaccination requirements.

b) **Agree** to a recommendation from the Ministry of Health (the Ministry) that we shift away from a set definition of 'fully vaccinated' against COVID-19, to focus on 'maintaining an up-to-date vaccination status'. **Yes/No**

c) **Note** CV TAG has expressed the opinion that extension of the requirement for a booster dose beyond those already covered by Vaccination Orders would require a change to the intent of requirements (away from reduction of transmission) in order to be justified.

d) **Note** that should Vaccine Ministers decide in future to require boosters to maintain vaccination status, the Ministry recommends current vaccine passes continue to be valid until their current expiry date, but with new passes made available as people become due their booster dose (or available as soon as the system changes are in place for those who already have received their booster – proposed to be in place by 1 April 2022).

e) **Note** the Ministry's Data and Digital team has begun the work necessary to prepare the My Vaccine Pass system to recognise boosters and produce renewed passes, acknowledging this may not be required.

f) **Note** CV TAG has expressed a strong view that no vaccine requirements (formal or informal) should be applied for those under 18 years of age.

g) **Note** the addition of a booster requirement to maintain a valid My Vaccine Pass, will not impact affected workers under the Vaccination Order as these workers are already required to receive a booster.

h) **Note** that now Omicron is established as the dominant strain circulating in New Zealand, the rationale for more stringent requirements for international arrivals has weakened, and any changes to vaccination requirements for arrivals to New Zealand must consider the domestic context, be evidence based, proportionate and justifiable.

i) **Note** the COVID-19 Vaccination and Immunisation Programme (CVIP) continually updates the forecasts and modelling on vaccine supply and will continue to keep Vaccine Ministers updated.

j) **Note** the Ministry will continue to consider the most appropriate way to manage people on alternative vaccination pathways, and work to have options developed for Vaccine Ministers to consider, should any decision be made to include boosters in vaccination requirements.

k) **Note** the Ministry will provide further advice to support decision making, to Vaccine Ministers in early March 2022, once the Department of Prime Minister and Cabinet reviews of the use of My Vaccine Pass and the COVID-19 Protection Framework are complete.

l) **Note** the information provided here is relevant and up to date at this time, but as the situation could change rapidly, different or additional considerations may need to be taken into account by the time the DPMC review is complete.

m) **Note** officials are available to meet to discuss the contents of this paper.

Dr Ashley Bloomfield
Director-General of Health
Ministry of Health
Date: 18 February 2022

Hon Grant Robertson
27/02/2022

Requiring COVID-19 vaccine boosters to maintain vaccination status in the New Zealand context

Background

8. The Omicron variant of COVID-19 is now spreading in New Zealand communities and has been established as the dominant variant circulating. We are currently in the second stage of our Omicron response strategy, where cases are continuing to be confined as much as possible, but numbers are increasing rapidly. High uptake of COVID-19 vaccine booster doses will help to reduce the number of people with symptomatic illness, those who require hospitalisation, and the burden on the health system.

9. The Government has utilised a number of tools to manage the spread of COVID-19 over the course of the pandemic. Tight border settings, domestic restrictions and public health measures have served us well. More recently high uptake of vaccinations has been critical to maintain our low hospitalisation and death rates, relative to other countries. With the borders beginning to re-open this month, and with the Omicron variant established in the community, we must continue to adapt our response to the changing circumstances.

10. As at 14 February 2022, 94 percent of the eligible population have completed a primary course of a COVID-19 vaccine schedule, and approximately 61 percent of the (currently) eligible population have received a booster dose.

11. International studies show that vaccine induced immunity against symptomatic illness (from the Pfizer and Moderna vaccines), wanes from three to four months after completion of a primary course, and particularly by six months. Booster doses of Pfizer (and Moderna) vaccines have been shown to lift vaccine induced immunity again to provide levels of protection that significantly reduce hospitalisations and death, including from the Omicron variant.

12. This paper provides advice on the implications of including a booster in further vaccination requirements and provides options for implementation should Vaccine Ministers decide to require boosters to maintain up-to-date vaccination status.

Comment

Replacing the term "fully vaccinated" with "maintaining up-to-date vaccination status"

13. Internationally recognition is growing that referring to being "fully vaccinated" against COVID-19 is no longer helpful in an environment where an ongoing COVID-19 vaccination programme may be required. For example, Australia will replace the term 'fully vaccinated' with 'up to date' in respect of COVID-19 vaccination status for domestic use. The date of entry into force has not yet been determined but "by the end of March" has been recommended by ATAGI.

14. For the purpose of the New Zealand context, the Ministry recommends a shift away from a set definition of "fully vaccinated" against COVID-19, to a focus on "maintaining up-to-date vaccination status".

15. This shift will help future decisions on updates to vaccination requirements to remain flexible and help to communicate that vaccination against COVID-19 is not an end point, but a

potentially ongoing vaccination programme. Additionally, "vaccination status" is more inclusive of people who are exempt from COVID-19 vaccinations, or who require different dose or vaccine schedules.

16. We seek agreement from Ministers that we shift away from a set definition of "fully vaccinated" against COVID-19, to focus on "maintaining up-to-date vaccination status".

With arrival of the Omicron variant, boosters are intended to maintain population protection and minimise its spread

17. In line with the aims of the Government's COVID-19 Protection Framework (CPF), the intent of the booster programme is to keep the spread of COVID-19 and hospitalisations as low as possible, protect people from the virus, minimise significant health impacts, and support infection prevention and control. Vaccination, including boosters, is a key tool in the CPF.

18. The arrival of the Omicron variant has required us to respond rapidly, and to do everything we can to increase booster uptake to help maintain population protection and to protect our most vulnerable, particularly as we have moved away from the elimination strategy to one where we aim to minimise the impacts of COVID-19 in our communities.

19. Cabinet's recent decision to reduce the dose interval for a booster, to three months from completion of a primary vaccine course, demonstrates the need for the vaccination programme to be agile and responsive, and introducing a requirement for booster doses would support the intent of that decision.

20. However, we need to consider whether introducing further booster requirements (beyond those already in place for affected workers under the Vaccination Order) is strictly necessary to achieve the overall public health aims as outlined above.

21. As the Omicron variant spreads throughout the community and more and more people are exposed, infection induced immunity becomes an additional factor to consider.

CV TAG has expressed the view that introducing a booster requirement to maintain an up-to-date vaccination status would be difficult to justify

22. The Ministry has received advice from CV TAG this week as follows.

23. CV TAG's view is that vaccine mandates, vaccine passes, and different isolation/testing requirements for arrivals to New Zealand have been previously justified through the protection of others mainly via a reduction in transmission.

24. The Omicron variant is highly transmissible, and vaccination (primary course or booster) appears to provide less protection against infection with Omicron than against previous variants.[1] This is important because protection against infection is one way a vaccine can reduce transmission. There are no data currently available about whether the vaccine prevents or reduces onward transmission of Omicron once a vaccinated person is infected, which is the other way a vaccine could reduce transmission.

25. However, data to date shows that protection against symptomatic and severe disease caused by Omicron is restored (to levels similar to or higher than a primary course) after a booster.

[1] **COVID-19 Omicron Update – 03 February 2022.**

This will result in increased personal protection for vaccinees against illness and could potentially reduce strain on the healthcare system at the peak of an Omicron wave if a substantial number of people are boosted.

26. Additionally, it is anticipated that in the coming weeks, many people will be infected with Omicron and this is likely to produce an immunological boost in these people.

27. Because of these issues, CV TAG has expressed the opinion that introducing boosters to maintain up-to-date vaccination status would be difficult to justify on the basis of a reduction of transmission. They consider any extension of the requirement for a booster beyond those already covered by Vaccination Orders would require a change to the intent of requirements (away from reduction of transmission) in order to be justified.

There are a number of interconnected implications of any decision to require booster doses to maintain up-to-date vaccination status

28. Decisions on whether to introduce, and when to introduce a booster requirement to maintain vaccination status, is not straight forward and has a number of interconnected implications:

    a. Managing the validity of vaccine passes – including for those under 18 years of age (noting the passes' central role in the COVID-19 Protection Framework).

    b. Interactions with requirements for international arrivals and the timing of the Reconnecting New Zealand (border opening) stages (and meeting international vaccination certificate requirements)

    c. Ensuring any new requirements are no more burdensome than the worker mandates under the Vaccination Orders, and

    d. Securing vaccine supply – ensuring we have adequate supply of the right vaccines to meet demand.

29. Each of these implications are discussed below.

Implications for COVID-19 Vaccine Passes

30. The Department of Prime Minister and Cabinet (DPMC) is undertaking a review of the use of My Vaccine Passes (MVP) the details of which the Minister for COVID-19 Response will report back to Cabinet on in early March 2022. This review will cover the immediate operational challenges of the use of the pass system, focussing on key themes and issues related to the operation of MVP to date and whether there are changes that could be made, either to the passes themselves or the policy surrounding their application, to address these concerns.

31. DPMC is also undertaking a broader review of the CPF. As part of this review, the future use of MVPs will be considered. Drawing on information from the above-mentioned preliminary review, and latest public health advice, DPMC will assess whether restricting freedoms based on vaccination status continues to be a justified and proportionate element of our COVID-19 response.

32. Vaccine passes have served a public health purpose up until now to help prevent the spread of COVID-19 and to support the COVID-19 Vaccine and Immunisation Programme (CVIP) to achieve population protection.

33. With a now highly vaccinated population, consideration needs to be given to whether vaccine passes are still serving their intended purpose. The DPMC reviews, informed by ongoing advice from the office of the Director of Public Health, will help support these considerations.

34. The current passes expire starting from mid-May, and all of them by 1 June 2022. The pandemic has taught us the situation on the ground can change rapidly and our response must remain agile. For that reason, we recognise that by mid-May the situation we are facing may be quite different. We may be facing a new variant, or we may be seeing the end of the Omicron 'wave', with the need for vaccine passes falling away.

35. Equally, with Omicron currently spreading rapidly in the community we anticipate there may be a need to re-new the passes, and therefore work is required now to prepare for renewal.

System changes will be needed should boosters be included which will require a 'newer version' of vaccine passes

36. The MVP system can be updated to recognise booster doses and auto-generate a new pass to be downloaded, auto emailed, or retrieved through assisted channels (call centres or vaccination sites).

37. A minimum viable product with changes for a 'new version' of a My Vaccine Pass could be put in place within two weeks of a decision being made to proceed (note preparations have already begun as noted below). This would include minimal visual changes to the pass to support visual verification and changing the 'system rules' which will shift the pass expiry to align with any new rules related to boosters.

38. Learnings from the launch of My Vaccine Pass allow us to see the greatest challenge will be getting the population through the renewal process without overloading the system and causing frustration.

39. There are two options for implementation of the 'new version' of the vaccine passes.

    a. **Option one *[recommended]*:** new version of passes will be issued or accessible based on the new rules and will be delivered to phase out or replace current passes once they reach their current expiry dates – either mid-May or 1 June 2022).

    b. **Option two:** require passes to be expired earlier than their current expiry dates, with the new version of passes to be requested/reissued with new expiry function based on the 'new rules' outlined above.

40. The Ministry advise the public would require 3-4 weeks to replace their vaccine passes once available. This would give people time to get their booster dose, and then request and download the 'new version' of the pass. This would also allow for support services to be in place for those who require assistance to access a new pass.

41. This would also allow time for a public communications campaign to explain the updated system and requirements, and time for businesses to update their systems, especially those who have integrated the vaccine pass verifying scanner into their own operating systems.

42. A total of 5-6 weeks is estimated to enable all changes and embed the new passes, which will require a reprioritising of resources.

43. When My Vaccine Pass was released people had just 17 days to get their pass before the traffic light system began, which created significant challenges for the Ministry and a certain level of anxiety among the public. Therefore, should a decision be made to introduce a

booster requirement to maintain a valid vaccine pass, the Ministry would not recommend Option two above, which would result in a sudden cancellation of passes and subsequent scramble to request and download the new version.

44. Should a decision be made to require booster doses, the Ministry would recommend Option one above – to renew vaccine passes to align with any vaccination requirements (including booster doses), with new passes only **required** once current passes reach their expiry dates.

45. However, issuing new passes would begin before the expiry of the existing ones as people receive their boosters and become eligible, which will allow for a longer lead in time for people to get the passes before their current passes expire. People who have already received their booster would be able to access their new pass as soon as the system changes are in place.

46. New passes could be issued with a further 6-month expiry from the date of the user's booster dose (or completion of primary course if they are recently vaccinated) and would have a different visual look to the current passes to ensure people don't continue to use their old one.

Additional considerations will need to be given to transition, compliance, exemptions other issues relevant to vaccine passes

47. Regardless of which option for implementation is taken the transition stage between the old passes expiring (as people reach their current expiry dates) and the new passes being issued will have to be managed carefully to avoid confusion over which passes are valid and who can access services.

48. Those with clinical vaccination exemptions will also need to be able to access a new pass (which may be dependent on them receiving an up-dated exemption approval from the Director General of Health via the panel approval process), and so the system rules will be built to work for anyone, no matter where they are in their vaccination journey.

49. Consideration may also need to be given to improving compliance monitoring and the verification of vaccine passes (such as mandatory scanning with verifier or spot checks against photo ID) as the Ministry is concerned that continuing to require vaccine passes without improving compliance reduces the value of their use.

50. Should a decision to renew passes be made, the passes would need to be rolled out from 1 April 2022, therefore (without pre-empting any decision), the Ministry has started work on building the required system changes now, acknowledging that pending a decision from Vaccine Ministers, this work may not be required.

Vaccine passes for 12-17 year olds

51. Booster doses have only been approved by Medsafe for people aged 18 years and over. Currently, s 9(2)(b)(ii) [redacted]

52. CV TAG have previously advised that booster doses should not be required for this age group and this week have expressed that they have a strong view that no vaccine mandates (formal or informal) should be applied for those under 18 years of age.

53. Should booster doses become a requirement to maintain vaccination status, the requirements for 12 to 17-year-olds would need to be different from those for 18 years and over (i.e requirements for 12-17 would remain as they are).

54. Differentiation of pass types will add complexity to the current service and would take additional time to develop and implement.

55. Booster requirements internationally vary, but at this stage most countries are not requiring booster doses for 12-17 year olds. A handful of countries such as Australia have approved booster doses for 16 – 17-year-olds, and the United States and Israel have approved the use of boosters in 12-18 year olds.

Additional issues with vaccine pass renewal - and potential solutions

56. As outlined above, the situation for 12-17 year olds with regard to vaccine passes is not straight forward. Consideration needs to be given to whether the public health rationale for requiring vaccine passes is still relevant for 12-17 year olds.

57. Should the decision be made to require boosters and renew vaccine passes, one potential solution for the 12-17 age group would be to maintain passes for them with a rolling expiry in case the vaccination requirements for this age group change in the future.

58. A further concern is how to manage the expiry of passes for the cohort of people who will already have reached six months since their booster when the current passes expire on 1 June 2022. Many border and health care workers received booster doses in November 2021, and many others, including many over 65-year-olds will reach six months since their booster by the end of June 2022.

59. This means a large cohort of people could have a very limited expiry on any new passes. There is still very limited evidence and data on providing a second booster dose, and few countries are doing so. Therefore, rolling out second doses of boosters is not currently planned.

60. One solution for this problem would be to provide an automatic 90-day extension to those passes that would auto-generate and take them through to September 2022. This would provide time to gather further evidence and data to support any future booster decisions, or alternatively by September (with the peak of Omicron infections having passed), the need for vaccine passes may have fallen away.

Implications for Vaccination Orders

61. On 20 December 2021 Cabinet agreed to an amendment to the COVID-19 Response (Vaccinations) Order 2022 to require affected workers under the Order to receive a COVID-19 vaccine booster dose by 6 months from completion of their primary vaccine course.

62. The addition of a booster requirement to maintain a valid My Vaccine Pass, will not impact affected workers under the Order as these workers are already required to receive a booster dose. Some employees have used their My Vaccine Pass to provide evidence of vaccination to employers, but they can also use other methods such as showing employers their My Covid Record, providing a letter from their General Practitioner, or some employers are utilising the COVID-19 Immunisation Register to verify employee vaccination status.

63. It is important that should the booster requirement be extended to the wider public, that the requirements are no more burdensome than those for affected workers as set out in the Order.

Implications for international arrivals

64. On 20 January 2022 DPMC provided the Minister for COVID-19 Response with advice on implementing a booster requirement for international arrivals in light of the sharp increase in cases being detected at Managed Isolation and Quarantine (MIQ) via the air border, and to further mitigate the risk of Omicron entering the community. [DPMC-2021/22-1201 refers].

65. The advice noted that any strengthening of vaccination requirements for arrivals would need to be justifiable and proportionate. It would need to weigh up the likely public health benefits against the ability of travellers being able to meet the requirements and operational challenges of verifying the booster requirement.

Globally boosters are not widely available, and exemptions will need to be in place if boosters were to be required for international arrivals

66. As booster programmes are not yet widely available globally, there would also need to be an exemptions system in place which would have disproportionate impacts on travellers from some countries. Information compiled by the Ministry of Foreign Affairs and Trade (MFAT) suggests there are only 77 jurisdictions where it could be reasonably considered that there is access to a primary course of vaccination and where booster programmes have started to be rolled out. A booster requirement would also impact arrivals from some Pacific countries, most of which are still focused on rolling out primary courses to their populations.

67. Limited access to booster programmes would prove even more challenging for any New Zealanders needing to travel to New Zealand at short notice, and for those travelling from countries where the systems and procedures for recording of booster doses on existing certificates are not established.

The rationale for more stringent requirements for international arrivals has weakened as community cases of Omicron escalate

68. There is currently no data on the effectiveness of boosters for the vast majority of vaccines on the approved list for arrival to New Zealand. If a booster was to be required, it would need to be defined for each of the approved vaccines (currently 33) in the context of the Omicron variant, including the timing and number of doses, consideration of heterologous (mixed) schedules, and the impact of previous infection.

69. Instead, officials recommended that consideration be given to introducing a requirement for a maximum interval between a final primary course or booster and arrival in New Zealand.

70. The Minister for COVID-19 Response considered the briefing on 29 January 2022, but did not sign any recommendations, instead noting "*…it will be hard to justify boosters for CVC access but not for people visiting New Zealand. If equity of access is the issue, could we require boosters within a window of arrival?*"

71. Over the past three weeks the domestic situation has changed considerably, and Omicron is now established as the dominant strain circulating in New Zealand communities. This means the rationale for more stringent requirements for international arrivals has weakened as

community cases escalate. It is important that any changes to vaccination requirements for arrivals to New Zealand consider the domestic context, are evidence based, are proportionate and are justifiable.

72. In terms of managing different vaccination schedules and booster requirements for international arrivals, CV TAG have advised that evidence of three doses of a World Health Organisation (WHO) listed vaccine should be adequate to meet the 'boosted' standard in the New Zealand context.

73. The requirements for international arrivals are being kept under review and further advice will be provided to Ministers in due course.

Implications for COVID-19 vaccine supply

74. Booster uptake is now well established and is running at 61 percent of eligible people (as at 14 February 2022).

75. The COVID-19 Vaccination and Immunisation Programme (CVIP) continually updates the forecasts and modelling, and currently estimates a potential supply gap from March 2022 of up to 115,000 doses as well as continued supply pressure in the first half of 2022.

76. On 1 February 2022, Vaccine Ministers agreed to work with Pfizer to bring forward delivery of 1.25 million doses into the first quarter, and an additional 0.25 million doses in the second quarter (meaning 1 million doses will be delivered in the second quarter). Following further advice on the amendment agreement, the Director General of Health will be invited to sign the agreement.

77. There will be a two-week period when availability of Pfizer across New Zealand is under 300,000 doses (average 162,000 doses). This may pose an operational risk of slowing the administration of the programme. However, the programme is able to mitigate this by managing central distribution of stock, monitoring doses per vial utilisation, and through the timing of our donations to countries in the Pacific region.

78. Further advice will continue to be provided to Vaccine Ministers to manage New Zealand's potential COVID-19 immunisation needs in 2022.

Implications for people on alternative vaccination pathways

79. The 'typical' vaccination pathway of a two or three dose primary course with subsequent booster, utilising the Pfizer vaccine, may become challenging to complete for an increasing number of the population who need more flexibility.

80. This need for flexibility primarily reflects their clinical characteristics, such as experience of COVID-19 infection between vaccinations, serious adverse event, or pre-existing clinical condition. In these situations, specialist clinicians may reasonably recommend reduced doses, alternative vaccines, extended dosing intervals, or that future COVID-19 vaccines are contra-indicated altogether.

81. The need to accommodate alternative pathways will also become more pressing as increasing numbers of people vaccinated overseas come into the country. In addition, we want to ensure we support New Zealanders to contribute to our vaccine clinical trials occurring here.

82. Currently a proportion of these scenarios are managed through a Temporary Medical Exemption panel. This may not be the appropriate mechanism to manage the scale and

complexity of these alternative pathways, and the variety of scenarios that may be presented. Other options would be to support an individual's clinician to make an assessment around vaccination requirements (with or without oversight from the Ministry), or to expand the current Ministry of Health medical exemption framework and infrastructure.

83. The Ministry will continue to consider the most appropriate way to manage alternative vaccination pathways and work to have options fully developed for Vaccine Ministers to consider should any decision be made to include boosters in vaccination requirements.

Looking ahead and managing vaccination requirements beyond the next six months

84. As the pandemic wears on the social licence to maintain public health and vaccination requirements will likely wane. The DPMC reviews will help to provide insights on public acceptance of continued use of the MVP system to manage people's vaccination status versus effectiveness to maintain population protection.

85. Consideration needs to be given to the social license risk to the policy intent of the vaccination programme, and the resource risk to the ongoing management of the programme.

86. Additionally, continual amendments to regulations such as the Vaccinations Order may not be sustainable and a modified method of updating requirements as we respond to any further COVID-19 variants and each new stage of the pandemic may be required.

87. There is evidence to suggest that the next variant of concern may come from a country with high immunocompromised rates and low vaccine coverage. As we race to maintain high vaccination coverage domestically, we also need to consider global vaccine inequity and that it has a direct impact on New Zealand's own interests to end the pandemic.

88. Advice is being prepared for Vaccine Ministers on any potential setting changes that may be required under Phase 3 of the Omicron response strategy.

Human Rights

89. This paper does not seek any decisions but provides an update on the further advice being sought and further considerations being undertaken. Any consideration of requiring booster doses domestically to maintain vaccination status will have human rights implications similar to those considered under the current Vaccination Orders.

90. Whether or not a booster requirement is placed on non-citizens before they are able to come to New Zealand, no human rights issues arise. Non-citizens do not have a right to enter New Zealand, and they do not have rights under the New Zealand Bill of Rights Act 1990 (BORA) until they get to New Zealand.

91. If a booster requirement was put in place, non-citizens could not be forced to be vaccinated if they managed to board a plane to New Zealand, as they would have the right to refuse medical treatment, affirmed by section 11 of BORA. However, it would likely be a justified limit on that right to deport anyone who attempted to enter New Zealand without meeting such a requirement, given the importance of avoiding the creation of outbreaks in New Zealand that would have the potential to overwhelm the healthcare system.

Equity

92. Eligibility and access to boosters will be a key consideration of any discussion regarding including booster doses in the requirements to maintain vaccination status.

93. Current experience from the CVIP shows that additional levers are required for Māori and Pacific peoples to achieve the same vaccination targets as non-Māori, non-Pacific people.

94. CVIP has highlighted that the factors below are key to contributing to equitable vaccine uptake by Māori and Pacific people:

    a. access to vaccinations,

    b. access to trusted information sources to mitigate misinformation, and

    c. Māori health and Pacific health providers are well resourced and supported by their District Health Boards (DHBs) to deliver to their communities

    d. Non-Māori and non-Pacific health providers working to achieve equitable outcomes in their community and supporting a whānau ora approach.

95. We know that historically Māori and Pacific have been disproportionately affected by vaccine preventable diseases and that in general, Māori and Pacific peoples have low vaccination rates.

96. Including boosters in the requirements to maintain COVID-19 vaccination status may have a positive effect by protecting Māori and Pacific people, who are in roles affected by the Vaccination Order.

97. This change may indirectly protect people at high-risk of contracting COVID-19 such as tamariki and rangatahi who are not or yet to be vaccinated; particularly given the young demographic of Māori and Pacific people.

98. There may also be employment implications for Māori and Pacific peoples if not boosted as termination of their job will lead to loss of income, and in some cases this would be the sole income for the household.

Te Tiriti o Waitangi implications

99. In considering booster dose requirements, we need to be clear about how we would be protecting Māori to honour our Te Tiriti o Waitangi (Te Tiriti) obligations. We can use the Te Tiriti principals to guide this work.

    a. Tino rangatiratanga

    b. working in **partnership** with iwi and Māori health stakeholders particularly as they would have insights into issues and improvements to vaccine uptake for Māori.

    c. It is likely that an amendment to include boosters to the fully vaccinated definition will support health system resilience, minimise community outbreaks and any associated 'Red Light' setting restrictions. This is critical to minimising and addressing existing inequities and is consistent with Te Tiriti principle of **active protection**.

    d. **Equity** by ensuring that no changes would impose on the existing leverages made to achieve equitable vaccine uptake for Māori.

100. As COVID-19 has more disproportionate effects on Māori, it is important that there is targeted support for Māori in the domestic booster vaccination campaign, particularly in light of Omicron and the higher risk of transmission.

Next steps

101. The Ministry is working on further advice to support decisions on whether to require COVID-19 boosters to maintain up-to-date vaccination status.

102. The Ministry will continue to prepare for a renewal of vaccine passes, (understanding they may not be required) pending any decision to require boosters to maintain up-to-date vaccination status.

103. The Ministry will also continue to develop options to manage alternative vaccination pathways, and work alongside DPMC to provide options for international arrivals.

104. We will provide further advice to Vaccine Ministers in early March 2022, once the DPMC reviews referred to above are complete.

ENDS.

Briefing

Implementing an enhanced and expanded Influenza immunisation programme for 2022 in response to COVID-19

Date due to MO:	04 March 2022	**Action required by:**	07 March 2022
Security level:	IN CONFIDENCE	**Health Report number:**	20220324
To:	Rt Hon Jacinda Ardern, Prime Minister Hon Grant Robertson, Minister of Finance Hon Chris Hipkins, Minister for COVID-19 Response Hon Andrew Little, Minister of Health Hon Dr Ayesha Verrall, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Te Tumu-Whakarae mō te Hauora Director-General of Health	S9(2)(a)
Astrid Koornneef	Director, National Immunisation Programme	S9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Implementing an enhanced and expanded Influenza immunisation programme for 2022 in response to COVID-19

Security level:	IN CONFIDENCE	**Date:**	04 March 2022

To:
Rt Hon Jacinda Ardern, Prime Minister
Hon Grant Robertson, Minister of Finance
Hon Chris Hipkins, Minister for COVID-19 Response
Hon Andrew Little, Minister of Health
Hon Dr Ayesha Verrall, Associate Minister of Health

Purpose of report

1 This paper is to provide advice on the implementation plan and funding requirements for an enhanced and expanded Influenza immunisation programme for 2022.

Summary

2 With the borders closed due to the COVID-19 pandemic, New Zealand has had no to very low Influenza infections for the past two years. This reduction in infections is likely to have led to lower-than-normal immunity against the virus in the New Zealand population.

3 The presence of both influenza and COVID-19 (particularly Omicron) circulating in the community presents with an extraordinary situation where the risk of co-infection and the impact on an already stretched health system is high. In December 2021, Cabinet agreed in principle (subject to this advice) to expand the 2022 Influenza immunisation programme and directed the Ministry of Health (the Ministry) to work with Pharmac to provide this advice to Vaccine Ministers [CAB-21-MIN-0548].

4 This advice provides further information on delivering an enhanced implementation plan and funding requirements to commence rollout and options to expand 2022 Influenza immunisation programme ("the 2022 programme"). Subject to this advice, Cabinet has authorised the Prime Minister, Minister of Finance, Minister for COVID-19 Response and the Minister of Health to jointly approve the drawdown of funding required for the 2022 programme from the COVID-19 Response and Recovery Fund (CRRF).

5 It is expected that s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j) over two financial years will be required to support the expansion and implementation of the 2022 programme.

6 Your agreement is sought for the 2022 programme as contained in the advice.

Recommendations

We recommend you:

		Prime Minister	Minister of Finance	Minister for COVID-19 Response	Minister of Health	Associate Minister of Health
a)	**Note** that there is a higher risk with the 2022 influenza season as our borders reopen which may have a greater impact on New Zealanders and an already stretched health system					
b)	**Note** that the currently publicly funded influenza vaccination is targeted at people at highest risk of serious illness, namely, people aged 65 years and over, pregnant people, those with certain chronic or serious conditions and young children (under four years old) with a history of serious respiratory illness					
c)	**Note** in December 2021, Cabinet agreed in principle (subject to this advice) to expand and enhance the 2022 Influenza immunisation programme and directed the Ministry to work with Pharmac to provide this advice to Vaccine Ministers [CAB-21-MIN-0548 refers]					
d)	**Note** Cabinet also authorised the Prime Minister, Minister of Finance, Minister for COVID-19 Response and the Minister of Health to jointly approve the drawdown of funding from the COVID-19 Response and Recovery Fund (CRRF) for costs related to expanding the influenza programme for 2022, subject to this advice [CAB-21-MIN-0548 refers]					
e)	**Agree** to an enhanced influenza immunisation programme in 2022 that seeks to maximise uptake and increase demand in the current eligible population at a total cost of s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j), including allowing the Ministry to reimburse the costs for immunising all non-District Health Board (DHB) health and disability workers against influenza	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**
f)	**Note** that in addition to implementing an enhanced influenza immunisation programme in 2022, Ministers could indicate a preference to expand eligibility for the 2022 programme for Pharmac's consideration.					

	Prime Minister	Minister of Finance	Minister for COVID-19 Response	Minister of Health	Associate Minister of Health
g) **Indicate** a preference to expanding eligibility for publicly funded vaccinations for 2022 as part of the COVID-19 response to either:					
Preference 1 – Māori and Pacific peoples aged 55 to 64 years (*Recommended*)	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**
OR					
Preference 2 - Children aged 6 months to 5 years *(Not recommended)*	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**
h) **Approve** the following changes to appropriations to give effect to the decision in recommendation e) above, with a corresponding impact on the operating balance and net core Crown debt:	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**	

Vote Health	**$ millions – increase / (decrease)**				
Minister of Health	**2021/22**	**2022/23**	**2023/24**	**2024/25**	**2025/26 & outyears**
Departmental Output Expense:			-	-	-
Managing the Purchase of Services (funded by Revenue Crown)	2.250	1.250			
Non-Departmental Output Expense:					
Public Health Service Purchasing	s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)		-	-	-
Total Operating	s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)		**-**		**-**

i) **Agree** that the expenditure in recommendation h) above be charged against the COVID-19 Response and Recovery Fund	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**
j) **Agree** that the above changes to appropriations for 2021/22 be included in the 2021/22 Supplementary Estimates and that, in the interim, the increase be met from Imprest Supply	**Yes/No**	**Yes/No**	**Yes/No**	**Yes/No**

k) **Note** that all the funding profiles in recommendation h) above is based on the current estimate of when the costs will incur and dependent on the uptake of individual vaccine doses, there might be a need to seek in-principle transfers of some operating expenditure from 2021/22 to 2022/23 through Vote Health's June in-principle transfer process.

Rt Hon Jacinda Ardern

Prime Minister

...../...../.....

Hon Grant Robertson

Minister of Finance

...../...../.....

Hon Chris Hipkins

Minister for COVID-19 Response

15/ 3 /2022

Hon Andrew Little

Minister of Health

...../...../.....

Hon Dr Ayesha Verrall

Associate Minister of Health

...../...../.....

Robyn Shearer

Acting Director-General of Health

07/03/2022

I would like to see a greater emphasis on supporting the disability community to access influenza vaccines please. CH

Implementation plan on an enhanced and expanded influenza immunisation programme for 2022 in response to COVID-19

Context

We are in an extraordinary situation with the COVID-19 pandemic and as we prepare to reconnect to the world, we can expect to see more seasonal influenza in New Zealand

7 The reduction in influenza infections over the past two years is likely to have led to lower-than-normal immunity against the virus in the New Zealand population. The presence of both influenza and COVID-19 (particularly Omicron) circulating in the community presents an extraordinary situation where the risk of co-infection and impact on an already stretched health system is high.

8 Since the closure of the borders due to COVID-19, New Zealand has had low influenza infections (if any). Cabinet agreed for borders to reopen on 27 February 2022 [CAB-22-MIN-0008]. With our borders now reopen and with the removal of Managed Isolation and Quarantine Facilities (MIQF) there is an increased likelihood of importation of infectious vaccine preventable diseases, such as influenza.

9 The World Health Organization (WHO) has recommended countries to increase surveillance of influenza during the COVID-19 pandemic and to stepping up influenza vaccination campaigns to prevent severe disease and hospitalisation associated with influenza and prepare for co-circulation of influenza and COVID-19.[1] The impact of co-infection of influenza and COVID-19 is still unknown. Cases of co-infection are being detected in countries including the United States, Israel, Brazil, the Philippines and Hungary.[2]

10 The Institute of Environmental Science and Research (ESR) has advised that it is very likely once the borders re-open, that the rates of influenza infection will be higher. New Zealand saw an associated risk when the trans-Tasman travel bubble opened leading to increases of cases of respiratory syncytial virus (RSV).

11 The COVID-19 Vaccination Technical Advisory Group (CV TAG) advised that to help mitigate risks for New Zealanders from influenza during the COVID-19 pandemic, greater access to free influenza vaccine should be provided to combat the high public health risk from influenza.

12 As influenza begins to recirculate in New Zealand again while we are in the midst of the COVID-19 pandemic, a large portion of the population could become infected, leading to severe influenza-related illness and deaths. As we have seen with the recent RSV cases, this would put strain on our health services, perpetuate social and ethnic health inequities, and could impact our ability to care for people with other illnesses.

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1 Influenza Update N° 411 (24 January 2022) at https://www.who.int/teams/global-influenza-programme/surveillance-and-monitoring/influenza-updates/current-influenza-update

2 "*What is 'flurona'? Coronavirus and influenza co-infections reported as omicron surges*" (5 January 2022) at: https://www.washingtonpost.com/health/2022/01/05/flurona-coronavirus-flu-symptoms/

New Zealand's strategy on influenza immunisation is to protect high-risk individuals

13 New Zealand's influenza immunisation strategy focuses on protecting individuals at high-risk of serious complications, hospitalisation and death due to influenza. This is different to a population health strategy that seeks to provide broad population-protection. A key reason for this is the moderate effectiveness of influenza vaccines that makes taking and funding a population-protection strategy less desirable.

14 We are in an extraordinary situation with the COVID-19 pandemic and as we reconnect globally, we can expect more seasonal influenza cases in New Zealand. The fundamental principle for 2022 will be to address inequity by increasing uptake for those currently eligible for the publicly funded influenza vaccination while also considering the pressures on the health system.

15 Pharmac set the eligibility criteria for publicly funded immunisation as set out in the Memorandum of Understanding between the Ministry, Pharmac and DHBs. People who are not eligible are still recommended to get immunised and many employers cover the costs of immunising their employees. The following are currently eligible for publicly funded influenza vaccine:

- 15.1 people aged 65 years or older
- 15.2 pregnant women
- 15.3 people aged under 65 years (including children) with diabetes, most heart or lung conditions and some other illnesses
- 15.4 children aged 4 years or younger who have been hospitalised with respiratory issues.

16 Uptake in current eligible groups has historically been low. We estimate the total eligible population to be approximately 1.5 million people. While exact percentage uptakes cannot be determined, we estimate that approximately 50 percent of this group gets vaccinated each year. This estimate is based on claims made by providers each year and the knowledge that some people who would be eligible for free immunisation get it through their employer instead. (see **Appendix 1**).

17 The 2022 programme, starting on 1 April, will aim to maximise uptake in those people currently eligible, focusing strongly on those who are not immunised year-to-year. There will be a central focus on uptake in Māori and Pacific populations who have greater need (higher rates of pre-existing conditions) and routinely lower rates of influenza vaccinations across all age groups.

High uptake in eligible populations will ensure best use of vaccine supply

18 In 2021, we distributed 1.4 million doses around New Zealand, which is a broad indication of total uptake. For 2022, a vaccine supply totalling over 2 million doses is expected to be available for the New Zealand market. This includes a small amount, approximately 100,000 doses, that can only be sold privately (points 18.3 and 18.4 below).

- 18.1 A confirmed baseline of 1.7 million Afluria Quad / Alfuria Quad Junior from Seqirus, of which 300,000 doses are being underwritten by Pharmac.
- 18.2 Not yet confirmed - 200,000 doses of Afluria Quad and 20,000 doses of Afluria Quad Junior are being sought to support an enhanced programme. The estimated cost of

these additional doses is up to [redacted] at a per dose cost of [redacted] s9(2)(b)(ii),

18.3 [redacted] s9(2)(b)(ii), s9(2)(ba)(ii) doses of Fluad Quad (only for people 65 years of age and over) from Seqirus for private market only.

18.4 Between 60,000 and 80,000 doses from Sanofi for private market only. If there is high demand, Sanofi have indicated they could potentially provide more doses.

19 Each year, approximately 750,000 eligible people for a publicly funded influenza vaccine do not take up the opportunity to be vaccinated. Effort and resource are best directed at increasing uptake in this group, making best use of the total vaccine supply we have available for 2022. Table 2 shows approximately how many doses would be used to achieve varying levels of uptake in the eligible population. Even at 100 percent uptake, there will still be doses available for the private market, allowing a choice for those are not eligible to get immunised. In 2020, 878,128 vaccines were administered privately. For 2021, this number is expected to be between 600,000 and 700,000 but a final number is unknown until all unused vaccines have been returned and accounted for.

Table 2 – Dose requirements at varying levels of uptake in the eligible population, assuming population size of 1.5 million people

Uptake	Dose requirements	Doses remaining for private market
70 percent	1,050,000	950,000
80 percent	1,200,000	800,000
90 percent	1,350,000	750,000

20 This goal of enhancing uptake in the currently eligible population is supported by Pharmac who view this as the best way to improve public health outcomes for New Zealand.

Expanding eligibility for publicly funded vaccinations as part of our COVID-19 response in 2022

21 The Ministry has considered and provided various options with Pharmac for widening the eligibility criteria for the 2022 programme since September 2021 (see **Appendix 2**). As we are closely approaching the commencement of the 2022 programme (1 April), the Ministry considers the focus should now shift more towards strengthening and maximising uptake and demand within existing eligible groups, with consideration given to expand publicly funded vaccination for other populations for 2022 in view of our COVID-19 response. We seek confirmation as to whether Vaccine Ministers would want to expand eligibility only for the 2022 influenza programme as part of our COVID-19 response in addition to the wider enhanced implementation approach proposed by the Ministry to improve uptake. Should Vaccine Ministers be agreeable to expanding eligibility, then we request that Ministers indicate a preference as to which population group eligibility should be expanded to, for Pharmac to consider implementing. The two preferences are:

21.1 **Preference 1** – Publicly funded vaccination for Māori and Pacific Peoples (aged 55 to 64 years old) *(recommended)*

21.2 **Preference 2** – Publicly funded vaccination for children (aged 6 months to 5 years old) (*not recommended)*

22 Pharmac has indicated that from 4 March it intends to commence a public consultation process on the possibility of expanding the influenza vaccination eligibility to include Māori and Pacific peoples (aged 55 and over) for the 2022 influenza immunisation programme, noting the Pharmaceutical Schedule would be updated for 1 May.

Preference 1 - Publicly funded influenza vaccination for Māori and Pacific peoples aged 55 to 64 to further equitable outcomes (recommended)

23 Māori and Pacific peoples are over-represented in poorer quality and overcrowded housing leaving them at higher risk to influenza infection alongside COVID-19. Expanding the eligible group by lowering the age group for Māori and Pacific peoples could potentially remove some of the barriers and reduce the higher health risks associated.

24 Hospitalisations related to influenza affects Māori and Pacific peoples at a younger age compared to other ethnic groups. This strengthens the public health rationale to provide publicly funded influenza vaccinations for these groups. The burden of disease is not identical across all ethnicities therefore is not recommended here to lower the age of eligibility for other groups, where the risk is not as high.

25 CV TAG recommended that specific consideration be given to promoting and improving vaccine access to groups that have experienced disproportionate COVID-19 and influenza morbidity and mortality, as well as those with barriers to routine health care, especially for Māori and Pacific peoples.

26 A funding approach based on ethnicity is not unprecedented. Research has highlighted that mortality rates for Māori with type 2 diabetes was seven times higher than non-Māori and predicted that one in four Pacific peoples will have the disease within 20 years. Following this, Pharmac funded empagliflozin and dulaglutide for Māori and Pacific people with type 2 diabetes. This approach has made it easier for Māori and Pacific people to get the latest diabetes medication. A similar approach could be used for the influenza vaccine in 2022, focusing on the age of 55 to 64.

Current vaccine supply can support expansion for Preference 1

27 **Table 3** shows the estimated number of vaccines needed to immunise Māori and Pacific peoples aged 55 to 64. Population sizes have been adjusted to account for those with long term conditions who are already eligible for free vaccination.

28 Given uptake in previous years, the expected increase in uptake in 2022 and the size of the eligible population, it is unlikely that free vaccinations for this group would significantly increase the risk of short supply.

Table 3 – Dose requirements at varying levels of uptake for Māori and Pacific people aged 55 to 64 with associated costs. Assumed population size is 39,432 based on HSU and a proxy for long-term conditions

Uptake	Dose requirements	Administration Cost implication ($23.20 per dose administered)
70 percent	27,602	$0.640 million
80 percent	31,545	$0.732 million
90 percent	35,488	$0.823 million

Preference 2 - Publicly funded influenza vaccination for children aged 6 months to 5 years (not recommended)

29 The WHO recommends annual influenza vaccinations for children aged between 6 months to 5 years. The Australian National Immunisation Programme provides publicly funded influenza vaccines for children in this age group. Influenza can be dangerous for children younger than 5 years of age as they have a higher risk of hospitalisation and increased morbidity.

30 Immunising all children has the benefit of protecting them as individuals as well as reducing influenza transmission across the entire population. Māori and Pacific peoples, particularly children, live in multigenerational families and often in overcrowded conditions. They are at higher risk to influenza and COVID-19 infection and likely to transmit more easily into the community.

31 We do not currently recommend expanding eligibility to this group for 2022 mainly due to low uptake historically and more evidence required to determine scientific and public health benefits. This includes consideration of alternate vaccinations such as using Live Attenuated Influenza Vaccine (LAIV) which could be administered intranasally rather than by injection, which overcomes the challenges of deploying a trained workforce for such a large programme. LAIVs are currently not available in New Zealand but something which could be considered for future immunisation programmes.

32 While uptake could be improved through a targeted communications campaign, forecasting uptake remains very difficult and there is a high risk the forecasting could be higher than actual demand (see Table 4).

33 More vaccines would be required to support this group and this includes paediatric doses for those aged between 6 months and 3 years. Current supply does not have sufficient paediatric doses and Pharmac are unable to secure additional supplies through alternative sources to cover this population, at this late stage.

34 While we do not recommend this group for the 2022 programme, Pharmac has indicated it will consider this group for future programmes.

Table 4 – Estimated dose requirements at varying levels of uptake for children aged 6 months to 5 years with associated costs. Assumed population size is 316,325 based on HSU and a proxy for long-term conditions

Uptake	Dose requirements	Administration Cost implication ($23.20 per dose administered)
70 percent	221,428	$5.137 million
80 percent	253,060	$5.870 million
90 percent	284,693	$6.605 million

Implementation of the 2022 influenza immunisation programme (enhanced status quo)

35 Following on from the COVID-19 Vaccine and Immunisation Programme, the Ministry can continue building and strengthening our influenza immunisation programme. The Ministry will leverage off communications, analytics, and other delivery and operational functions and learnings. While this advice focuses on influenza, it is essential that we carry these over to the wider immunisation programme to provide optimal immunisation and public health outcomes for New Zealanders.

36 The following advice focuses on key parts of implementation that will most benefit uptake. **Appendix 3** provides an overview of all the elements considered in the implementation plan.

Focused whānau-centred approach to improve uptake for Māori and Pacific people and their whānau

37 A whānau-centred approach puts whānau needs and aspirations at the centre of services that are integrated and accessible. For immunisation, this means looking at the collective needs of the whānau by offering a wider suite of vaccinations rather than the individual needs.

38 The Ministry commissioned an evaluation of the 2020 Māori Influenza Vaccination Programme (MIVP), titled *More than just a jab.*[3] This evaluation identified this approach as key to increasing immunisation coverage, particularly for Māori and Pacific populations. This report and approach have since been a core consideration through the COVID-19 response and immunisation programme.

39 There are key elements to delivering on this approach. These require both long-term planning and implementation across the National Immunisation Programme (NIP) but can also be delivered in the short-term in the context of influenza vaccination.

39.1 Vaccinators need to consider the collective needs of the whānau when giving an influenza vaccination. For example, offering Measles Mumps Rubella (MMR) catch-ups

[3] https://www.health.govt.nz/system/files/documents/publications/more-than-just-a-jab-evaluation-of-the-maori-influenza-vaccination-programme.pdf

to tamariki who have missed their vaccinations, whooping cough vaccine to hapū māmā and COVID-19 boosters to whānau who are due them.

39.2 Develop a culturally competent and technically skilled workforce able to adopt a holistic, whānau-centred approach to supporting whānau aspirations. This will require long-term planning around vaccinator training, but also ensuring that Māori and Pacific health providers continue their vaccination services, building on their success in vaccinating whānau against COVID-19.

39.3 Remove unnecessary barriers that prevent providers from taking a whānau-based approach, for example pharmacist vaccinators are restricted to administering influenza to those aged 13 and over, despite being trained and competent to vaccinate younger age groups.

40 A key component of Māori Influenza and Measles Vaccination Programme (MIMVP) was that Māori-led services were stood up and work for Māori. Funding for the MIMVP had to be reprioritised from the Ministry's baseline and as it makes a valuable contribution to Māori influenza immunisation rates. Funding for the MIMVP was $9.5 million (in 2020) and $7.8 million (in 2021). This funding was provided to implement MIMVP. The cost of the influenza vaccine and administration is funded separately.

41 As these providers are currently funded to deliver COVID-19 initiatives (e.g. the Māori COVID-19 Community Fund) we envisage they are able to support the influenza immunisation programme without the need for additional funding.

42 The National Immunisation Programme (NIP) will support equity and encourage Māori and Pacific peoples to have general immunisations including MMR. The Ministry will in future seek funding for MIMVP through the regular budget process.

A boosted communication and promotional campaign

43 The influenza promotional campaign is being designed in-line with the strategy to increase uptake in eligible groups to protect high-risk populations and their whānau. The campaign has been led by the Immunisation Advisory Centre (IMAC) in past years but will be led by the Ministry in 2022.

44 There will be a continuation of the 2021 rebranded campaign titled *Treasure Our Whānau*. The Ministry is working with a creative agency, which is a Māori owned, globally aware advertising and design agency with experience working across Māori and Pasifika kaupapa. An example of the one of the posters, featuring kaumatua, is in **Appendix 4**.

45 The *Treasure Our Whānau* campaign was limited in reach and market time over 2021 as all communications had to be focused on COVID-19 response and vaccination. In 2022, the campaign will run for an expected eight weeks from late-March and include more communication channels in the media, particularly those which best reach Māori and Pacific people.

46 Alongside this campaign, the Ministry will also look to integrate influenza immunisation messaging into the COVID-19 campaign. This messaging will have a focus on winter protection as we move to a period where we will likely have both COVID-19 and influenza co-circulating.

47 The Ministry is mindful of vaccine fatigue and will be thoughtful of this for the Influenza campaign. Messaging will have to be carefully delivered to ensure it can be digested by every audience and delivers on its goal in influencing more people to get immunised.

48 To deliver this boosted campaign, the Ministry seeks your agreement to drawdown additional funding of $3 million. This is further detailed in the financial implications section.

National Immunisation Solution to enable accurate recording of influenza immunisation

49 The National Immunisation Solution (NIS) is a replacement to the National Immunisation Register (NIR) and will be available for providers to use by 1 April. Implementing the NIS will allow all influenza immunisations, both public and private, to be recorded in a database accessible by both the Ministry and immunisation providers.

50 This solution will give us a better national and regional picture of influenza immunisation coverage. Notably, this will be the first-time occupational health providers have been able to record influenza immunisations in a central depository. Regional planners will be able to develop better data-driven approaches to their influenza programme and providers themselves will be able to rapidly check their patient's immunisation status.

51 Development and implementation of the NIS is well underway.

Ensuring health workers are vaccinated as we continue to respond to COVID-19

52 The Ministry recommends all workers in the health and disability sector to be vaccinated. Healthcare workers, because of the nature of their work are at high risk from influenza and twice as likely to acquire influenza compared to non-healthcare workers. Healthcare workers have a professional responsibility to protect their vulnerable patients from influenza. Annual influenza vaccination of healthcare workers is likely to reduce illness among the patients and clients they care for.

53 Healthcare workers can transmit influenza without knowing they are infected. The Southern Hemisphere Influenza Vaccine Effectiveness, Research and Surveillance Study (SHIVERS) 2015 serosurvey showed that 1 out of 4 New Zealanders are infected with influenza each year, and that around 80 percent of those infected are asymptomatic. An asymptomatic carrier can unknowingly expose their family, co-workers and patients to the influenza virus.

54 The WHO, the United States Centre for Disease Control and Prevention, United States Advisory Committee on Immunization Practices, and the New Zealand Immunisation Handbook strongly recommend annual influenza immunisation for healthcare workers.

55 In New Zealand, DHBs cover the costs of influenza vaccination for their staff. There remains approximately 152,400 non-DHB health workers who must either pay for their own influenza vaccination or their employer chooses to offer free vaccination. To ensure all healthcare workers are immunised against influenza in 2022, the Ministry proposes to reimburse non-DHB employers and self-employed contractors the cost to vaccinate their workers.

56 Through 2020 and 2021, the Ministry operated a similar reimbursement scheme which had strict criteria where only employers who had not previously offered their staff free vaccination were eligible. While this provided benefit to some employers, it was also seen as unfair towards employers who have continued to do "the right thing" in ensuring their staff are vaccinated. For transparency and fairness, reimbursement in 2022 should be available to every non-DHB healthcare employer and self-employed contractor.

57 In previous schemes, the Ministry has reimbursed up to $35.00 (ex-GST), covering both the cost of the vaccine and the administration. We recommend continuing this maximum

allowance in 2022. This means the maximum spend on this reimbursement scheme would be $5.334 million.

Equity

58 Improving access to influenza immunisation to all New Zealanders by removing barriers is likely to have a direct and noticeable impact and reduce the equity gap. The proposals in this paper will provide greater protection for population groups at high risk, particularly Māori, Pacific peoples, disabled peoples, pregnant people and children.

59 There is a significant equity gap between coverage for Māori and Pacific peoples, and coverage for non-Māori, non-Pacific. Any supply constraints due to high demand will then focus on equity as a priority for Māori and Pacific peoples. Māori and Pacific peoples need to be prioritised based on increased vulnerability to infection, being more likely to be part of the essential workforce and living in multigenerational households. Doing more of the same would not be effective in eliminating inequities. Eliminating barriers, alongside targeted implementation, will improve vaccine uptake and be a step to directly address health inequities experienced (particularly with coverage among children).

60 Older people living in long-stay residential care homes or other long-stay care facilities are also more at risk where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality.

61 Disabled people are vulnerable to complications from influenza. Equitable access remains important for disabled people. The 2022 programme will better provide coverage also for disabled people as well.

62 Immunisation for pregnant people and children provide the best protection against common infectious diseases such as influenza. Maternal immunisation provides additional protection for infants who cannot be directly vaccinated. Immunisation of healthy children has the potential to reduce illnesses and related costs in both children and their families.

Te Tiriti o Waitangi implications

63 There continues to be a focus on increasing vaccination uptake for Māori. In the past, and particularly throughout the COVID-19 response, iwi, hapū and whānau have exercised, and in many cases exceeded, good practice in line with government guidelines to maintain the wellbeing of their own whānau.

64 The proposals in this paper support health system resilience and maintain community protection. This is critical to minimising and addressing existing inequities and is consistent with Te Tiriti principle of active protection.

Financial implications

65 On 15 December 2021, Cabinet authorised the Prime Minister, Minister of Finance, Minister for COVID-19 Response and the Minister of Health to approve and draw down from the COVID-19 Response and Recovery Fund for costs related to expanding the influenza programme for 2022, subject to approval of this advice [CAB-21-MIN-0548 refers].

66 The 2022 programme requires additional funding to support the boosted communications approach ($3 million), on-boarding of providers ($1.500 million), vaccinating all non-DHB health workers (up to $5.334 million) as well as programme support from the Ministry ($500,000). Table 5 below provides a breakdown of these funding required. Funding to on-

boarding providers will include training providers to use the NIS, development of resources and collateral to support providers. In addition to this, private providers may require incentives such as funding to use the NIS, as there is no legislative requirement for privately provided and privately funded influenza vaccinations to be entered into any national registry.

67 To support the 2022 programme, Pharmac is also securing a further 200,000 to 220,000 doses at a total cost of $1.900 million to $1.980 million.

68 Table 5 below provides a breakdown of these funding required:

Table 5: Breakdown of funding required

Cost breakdown based on activity area	Total cost	Cost expected in 2021/22	Cost expected in 2022/23
Enhanced 2022 Influenza immunisation programme (non-departmental expenditure)			
Vaccination of all non-DHB health workers	$5.334 million	$3.734 million	$1.600 million
Additional vaccines s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)	s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)	-	s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)
Provider On-boarding (i.e. training, resources, tools etc)	$1.500 million	$1.500 million	-
Subtotal			
Additional funding for implementation (departmental expenditure)			
Promotion and communications campaign (i.e. media, promotional material etc.)	$3.000 million	$2.000 million	$1.000 million
National Immunisation Programme support	$0.500 million	$0.250 million	$0.250 million
Subtotal for implementation	**$3.500 million**	$2.250 million	$1.250 million
New Funding Required			

69 We seek approval from delegated Ministers (Prime Minister, Minister of Finance, Minister for COVID-19 Response and the Minister of Health) to jointly approve drawdown of s9(2)(b)(ii), s9(2)(ba)(ii) [redacted] across two financial years s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j) in 2021/22 and s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j) in 2022/23) from the COVID-19 Response and Recovery Fund to cover the anticipated costs of the enhanced influenza vaccination programme in 2022 and to cover the cost of additional doses of the influenza vaccine, to be appropriated as shown in Table 6.

Table 6:

Vote Health **Minister of Health**	**$ millions – increase / (decrease)** **2021/22**	**2022/23**	**2023/24**	**2024/25**	**2025/26 & outyears**
Departmental Output Expense: Managing the Purchase of Services (funded by Revenue Crown)	2.250	1.250	-	-	-
Non-Departmental Output Expense: Public Health Service Purchasing	s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)		-	-	-
Total Operating	s9(2)(b)(ii), s9(2)(ba)(ii) and s9(2)(j)		**-**		**-**

70 Because the 2022 programme runs from 1 April to 31 December 2022, we expect some of the costs will incur in 2022/23 and the current funding profile reflects our best estimate. Dependent on the actual uptake of individual vaccine doses, there might be a need to seek in-principle expense transfers of some operating expenditure from 2021/22 to 2022/23 as part of Vote Health's June In-principle transfer process.

Pharmac Comments

71 Pharmac supports the option for an enhanced influenza immunisation programme that seeks to maximise uptake in the eligible population, including using a whānau-centred approach to increase uptake of other important vaccination programmes. This option sits within scope of Pharmac's current eligibility criteria.

72 Pharmac has sought urgent clinical advice from its Immunisation Advisory Committee and is running a truncated process regarding the possibility of expanding the influenza vaccination eligibility to include Māori and Pacific peoples (aged 55 years and over) for the 2022 influenza immunisation programme. Pharmac will publicly consult prior to making a decision before 1 April. However, Pharmac holds significant concerns about the practicality of implementation at this late stage before the 2022 programme starts on 1 April 2022. The implementation process will need to be carefully managed and well communicated.

73 Pharmac note that this approach is outside of its normal funding processes, which are well understood by the sector. However, Pharmac agrees that reopening the borders and COVID-19 (particularly Omicron) circulating in the community presents exceptional circumstances where out of the ordinary decision-making is necessary.

74 Pharmac will also be seeking further advice from its Immunisation Advisory Committee regarding the influenza immunisation programme for 2023, including whether the programme should be expanded for further population groups. Pharmac has already received advice to expand eligibility to include children (aged 6 months to 5 years) but does not have enough stock to support this approach for 2022. We will consider expanding eligibility to this additional group prior to confirmation of stock for 2023 influenza season.

Treasury Comments

75 Treasury supports the proposal to increase uptake of the influenza vaccine within the current eligible population, and the preference to expand the eligibility of the influenza programme to include Māori and Pacific peoples (aged 55 years and over).

Next steps

76 The Ministry will continue to work with stakeholders to implement the 2022 influenza immunisation programme, following Vaccine Ministers approval to the approach and drawdown funding.

ENDS

Appendix 1 – Influenza immunisation coverage 2017-2021

Influenza Coverage from 2017 to 2021 by Age Band and Ethnicity

Vaccination Year	Age band	Ethnicity: Total # population	Total # immunised	Total % immunised	Māori # population	Māori # immunised	Māori % immunised	Pacific # population	Pacific # immunised	Pacific % immunised	Non-Māori, non-Pacific # population	Non-Māori, non-Pacific # immunised	Non-Māori, non-Pacific % immunised
2021													
	All ages	5,087,407	884,435	17.4%	804,707	64,241	8.0%	331,089	33,800	10.2%	3,951,611	786,394	19.9%
	0 - 4	310,536	6,751	2.2%	85,613	660	0.8%	30,579	400	1.3%	194,345	5,691	2.9%
	5 - 19	965,455	38,372	4.0%	247,609	4,180	1.7%	89,851	2,061	2.3%	627,995	32,131	5.1%
	20 - 64	2,986,687	318,749	10.7%	415,609	29,949	7.2%	188,216	16,607	8.8%	2,382,861	272,193	11.4%
	65+	824,729	520,585	63.1%	55,876	29,453	52.7%	22,443	14,733	65.6%	746,410	476,399	63.8%
2020													
	All ages	5,029,318	1,146,821	22.8%	791,333	101,315	12.8%	325,393	55,476	17.0%	3,912,592	990,030	25.3%
	0 - 4	309,534	18,870	6.1%	84,973	2,533	3.0%	30,231	1,953	6.5%	194,329	14,384	7.4%
	5 - 19	962,501	82,138	8.5%	244,810	11,073	4.5%	89,686	6,137	6.8%	628,005	64,928	10.3%
	20 - 64	2,959,757	505,660	17.1%	408,685	55,806	13.7%	183,984	31,017	16.9%	2,367,088	418,837	17.7%
	65+	797,527	540,273	67.7%	52,865	31,919	60.4%	21,493	16,377	76.2%	723,169	491,977	68.0%
2019													
	All ages	4,959,925	829,113	16.7%	777,556	65,831	8.5%	319,816	36,201	11.3%	3,862,553	727,081	18.8%
	0 - 4	307,943	14,107	4.6%	84,303	1,721	2.0%	29,820	898	3.0%	193,820	11,488	5.9%
	5 - 19	958,978	55,497	5.8%	242,200	6,936	2.9%	89,623	3,090	3.4%	627,155	45,471	7.3%
	20 - 64	2,922,454	323,622	11.1%	401,052	34,198	8.5%	179,820	19,334	10.8%	2,341,582	270,090	11.5%
	65+	770,549	435,948	56.6%	50,001	22,984	46.0%	20,553	12,881	62.7%	699,996	400,083	57.2%
2018													
	All ages	4,879,556	754,941	15.5%	763,894	60,003	7.9%	313,921	35,408	11.3%	3,801,741	659,530	17.3%
	0 - 4	305,908	12,369	4.0%	83,634	1,473	1.8%	29,397	926	3.1%	192,877	9,970	5.2%
	5 - 19	951,829	50,574	5.3%	238,965	5,934	2.5%	89,367	2,975	3.3%	623,498	41,665	6.7%
	20 - 64	2,878,326	290,248	10.1%	394,039	31,793	8.1%	175,585	19,071	10.9%	2,308,703	239,384	10.4%
	65+	743,493	401,813	54.0%	47,257	20,810	44.0%	19,573	12,438	63.5%	676,663	368,565	54.5%
2017													

All ages	4,788,449	660,101	13.8%	749,473	54,516	7.3%	307,869	27,683	9.0%	3,731,107	577,902	15.5%
0 - 4	305,605	8,843	2.9%	83,296	1,137	1.4%	29,449	679	2.3%	192,860	7,027	3.6%
5 - 19	944,183	40,346	4.3%	235,574	5,404	2.3%	88,475	2,505	2.8%	620,134	32,437	5.2%
20 - 64	2,821,817	251,273	8.9%	385,874	29,410	7.6%	171,239	15,293	8.9%	2,264,704	206,570	9.1%
65+	716,844	359,687	50.2%	44,729	18,570	41.5%	18,706	9,213	49.3%	653,408	331,904	50.8%

Notes:

Source: National Immunisation Register, via Qlik

Date extracted: 27/08/2021

Ethnicity is prioritised and is taken from the latest recorded ethnicity information on the NHI

Age bands are based on age at the time of vaccination

Denominator data is taken from 2013 Census projections

The most recent 2 months of 2021 will be impacted by incomplete reporting which will understate true coverage.

The NIR is an incomplete record of influenza immunisation

Appendix 2 – Options proposed previously in expanding publicly funded eligibility

Options	Analysis	Pros	Cons
Māori and Pacific peoples aged 55 to 64 years old	• CV TAG recommended that specific consideration be given to promoting and improving vaccine access to groups that have experienced disproportionate COVID-19 and influenza morbidity and mortality, as well as those with barriers to routine health care, especially for Māori and Pacific peoples. • Māori and Pacific peoples are over-represented in poorer quality and overcrowded housing leaving them at higher risk to influenza infection alongside COVID-19. Expanding the eligible group by lowering the age group for Māori and Pacific peoples could potentially remove some of the barriers and reduce the higher health risks associated. • Hospitalisations related to influenza affects Māori and Pacific peoples at a younger age compared to other ethnic groups. This strengthens the public health rationale to provide publicly funded influenza vaccinations for these groups. The burden of disease is not identical across all ethnicities therefore is not recommended here to lower the age of eligibility for other groups, where the risk is not as high.	• Pharmac supports expanding eligibility to Māori and Pacific peoples aged 55 to 64 years old. • Easy to implement from Pharmac perspective as funding criteria would be simple to define. • No need to seek additional stock – volumes being brought to NZ would be sufficient to meet demand.	• In 2018 the Pharmac Immunisation Advisory Committee recommended that an application to expand access to this group be declined, however Pharmac staff think it is likely this recommendation would change if further advice was sought.[4]
Children aged 6 months to 5 years old	• Influenza can be dangerous for children younger than 5 years of age as they have a higher risk of hospitalisation and increased morbidity. This group is at highest risk of getting and transmitting influenza and with those under two are also at highest risk of adverse effects. The WHO	• 6 months to 5 years is at the highest risk of getting and transmitting influenza. • The WHO recommends annual vaccinations for children aged between 6 months and 5 years.	• Pharmac has no active funding application for this population group and has never received clinical advice from its Immunisation Advisory Committee on expanded access.

[4] Paragraph 4.25 - Immunisation Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) Meeting held on 16 May 2018 at: https://pharmac.govt.nz/assets/ptac-immunisation-subcommittee-minutes-2018-6.pdf

Options	Analysis	Pros	Cons
	recommends annual influenza vaccinations for children aged between 6 months to 5 years. • The availability of a publicly funded influenza vaccine will provide them and their whanau with some protection against influenza infection and hospitalisation. • The Australian National Immunisation Programme provides publicly funded influenza vaccines for children in this age group. The influenza disease burden is highest at the extremes of life and is significantly higher among Indigenous people of all ages and children under the age of 5 years.[5] • From a public health perspective, the Ministry recommends expanding the 2022 programme to include children 6 months to 5 years, given their vulnerability and being at higher risk of morbidity while not eligible for the COVID-19 vaccination.	• From a public health perspective, for 6 months to 5 years, given their vulnerability and higher risk of morbidity while not eligible for the COVID-19 vaccination. • It would likely be possible to secure additional paediatric doses to support this programme.	• There is historically low uptake for paediatric patients who are most at risk and who are already eligible (i.e. children with respiratory illnesses, immunocompromised, diabetes etc). This could be partially managed by a targeted communications campaign • Additional paediatric stock would need to be sought.
Children aged 6 months to 17 years of age	• Children who are vulnerable to severe complications from influenza are eligible for a publicly funded influenza vaccination. Immunising all children has the benefit of protecting them as individuals as well as reducing influenza transmission across the entire population. • Pharmac's Subcommittee, in 2018, considered that vaccination of primary school age children contributed to herd immunity and considered that a universal childhood influenza vaccination programme would only be achievable using Live Attenuated Influenza Vaccine (LAIV), with optimal delivery through a school-based programme. It further considered that universal childhood influenza vaccination would provide additional	As above	As above • It is unlikely that enough stock can be procured to support this option.

[5] https://pubmed.ncbi.nlm.nih.gov/29440502/and_https://pubmed.ncbi.nlm.nih.gov/28043223/

Options	Analysis	Pros	Cons
	health benefits with minimal additional risks. The Subcommittee considered that while vaccinated children may protect other groups, it was an ethical consideration that children themselves should also derive benefit from the vaccination.[6] • Expanding eligibility for children (aged 6 months to 17 years of age) aligns with our whānau centred approach and minimises the potential impact of influenza during a pandemic. With Māori and Pacific children living in multigenerational families and often in overcrowded conditions, the risk of transmission is higher particularly as children are usually the ones who spread the virus more easily into the community and in their homes. • Pharmac has indicated that this group would be a significant size. From a public health perspective there is a greater benefit to focus on the 6 months to 5 years old.		
People related to individuals who are currently eligible (whanau-based approach)	• The whānau-based approach will apply to those currently eligible for a publicly funded influenza vaccination. Their whānau will also be eligible for a publicly funded influenza vaccination, irrespective of where they live and their age. • Insights from MIMVP shows that vaccination rates, particularly for Māori, increased when providers are enabled to take a whānau-based approach (i.e. those who are eligible bring whānau members with them to the vaccination site, and they can be offered a vaccine as well). Evidence indicates that vaccination rates for Māori over the age of 65 years increased from	• Providers can identify some who are eligible for publicly funded influenza vaccinations. • Ability to target households.	• Pharmac not able to set up a funding process through the Pharmaceutical Schedule to enable all provider types to claim for otherwise non-eligible people. • Guidance for the sector and public messaging could be complex. • Experience from the COVID-19 whānau based approach, where uptake was not as high as anticipated.

[6] Paragraphs 4.14 and 4.15 - Immunisation Subcommittee of the Pharmacology and Therapeutics Advisory Committee (PTAC) Meeting held on 16 May 2018 at: https://pharmac.govt.nz/assets/ptac-immunisation-subcommittee-minutes-2018-6.pdf

Options	Analysis	Pros	Cons
	45.8 percent in 2019 to 59 percent in 2020. The equity gap was reduced to negative 8.4 percent from negative 12.1%. • A whānau-based approach has also been successfully implemented through the COVID-19 Vaccine and Immunisation programme (CVIP). Providers are already able to target whānau and identify who would be eligible for publicly funded influenza vaccinations. Equitable access and uptake would be improved through a whānau-based approach while at the same time minimising the burden on the health system. • Vaccination rates for Māori are increased when providers are enabled to take a whanau-centred approach and when they vaccinate anyone who shows up regardless of eligibility. The 2020 Māori Influenza Vaccination Programme report indicated that providers absorbed the cost of influenza vaccinations to people who were not covered in the criteria. This in tandem with the approach suggested by the Pharmac Subcommittee to improve coverage has led to the highest vaccination rates seen for Māori over the age of 65 years as the whole whānau shows up together for immunisations. These reports therefore suggested widening the eligibility criteria for Māori.		• Is inclusive of all those individuals eligible for the influenza vaccination rather than a particular targeted focus on those most at risk. • Difficult to forecast volumes and indicative costs.
People who are household contacts of people currently eligible	• This option can be implemented by extending the invitation for a vaccine to those who currently live with the identified person(s) and are eligible for publicly funded health and disability services.	• As per whānau based above and enhanced status quo.	• As per whānau based above and enhanced status quo.

Options	Analysis	Pros	Cons
	• This also allows for a whānau-centric approach (which is shown to be more successful in Māori and Pacific people).		
All people of Māori and Pacific ethnicity	• Providers can already identify people who are eligible for a funded influenza vaccination. • Cost has also been shown to be a barrier to getting immunised. Doing more of the same would not be effective in eliminating inequities. • This option would enable providers to vaccinate the whole whanau (whānau-centric approach), rather than only targeting individuals eligible for a funded vaccine.	• As per Māori and Pacific above and enhanced status quo. • Eliminating the cost barrier for this group, alongside targeted implementation, would improve their vaccine uptake.	• As per Māori and Pacific above and enhanced status quo.

Appendix 3 – Overview of the enhanced implementation plan

Implementation plan	
Stakeholder engagement	• A communications plan is being developed and external stakeholders have been identified. • The National Immunisation Programme is planning to meet with stakeholders in mid-February and then on a regular basis thereafter. • Engagement with Haurora Māori providers and Pacific Providers will commence mid-February and will be led by the Equity team. • New providers and vaccinators (i.e., Hauora Māori providers and Vaccinating Health Workers) will be enabled to deliver influenza immunisation, building on their success delivering COVID-19 vaccines providing provide new options for where and how people get immunised against influenza.
Communication and Promotional campaign	• Changes to the communications campaign in 2022 will be required in order to increase uptake of those currently eligible, include the expanded eligibility and achieve equitable immunisation coverage by targeting groups with lower vaccination rates such as Māori and Pacific peoples. • The current *Treasure our Whānau* campaign will be adapted to ensure promotion reaches all those eligible for a funded vaccine. Additional collateral has already been commissioned, to broaden promotional material to Pacific peoples and hapū māmā. • The influenza immunisation campaign should be driven through the tried and tested COVID-19 campaign channels and should adapt the *Treasure our Whānau* branding into the COVID-19 branding. This will strengthen the messaging by using well recognised branding and will ensure the public takes notice. • Messaging around concomitant delivery of the COVID-19 and influenza vaccines will be included so that the public and the sector are aware that it is safe to have them at the same time, rather than having to prioritise COVID-19 as happened last year, leading to low influenza vaccine uptake. • Consistent communications campaign will be created with coordinated and aligned messages for planned and reactive communications so that the health sector and the public receive the same information. • Continue to operate in a transparent, collaborative and constructive way with the public and sector stakeholders. • Outreach services that target Māori and Pacific peoples can be boosted in 2022 to increase uptake in these populations. With wider coverage

Implementation plan	
	of eligible groups for publicly funded vaccinations, Providers are then able utilise whānau-based approaches. • This campaign will continue to focus on improving uptake in people at high risk of serious illness and groups with historically low uptake, such as Māori and Pacific peoples.
Concomitant administration	• There is the opportunity concomitant administration of the influenza vaccination and COVID-19 vaccination, and other immunisations, where appropriate. This will be communicated with the sector. • MMR catch up vaccinations are now being offered alongside a number of COVID-19 vaccination providers. This approach will also have flow on effects to childhood immunisations. Where children, or their parents, present for an influenza vaccination, providers can offer or have a conversation about other childhood immunisations. This will help to opportunistically identify children who are behind on their childhood immunisations.
Workforce	• The programme will largely be delivered using the traditional workforce model (i.e. general practitioners, nurses and pharmacists) for publicly funded influenza vaccinations. • This model will be boosted by new providers and vaccinators (i.e. such as Hauora Māori providers and Vaccinating Health Workers). • This will provide other options for where people will get immunised against influenza. • Vaccinators who have been trained to administer COVID-19 vaccination will also be able to administer influenza, significantly boosting our vaccinator workforce. Note: Occupational Health Providers predominantly vaccinate in the private market. • General Practice will have the opportunity to record influenza vaccinations in the National Immunisation Solution (NIS) as well as their Practice Management Systems (PMS). • If a General Practice chooses to only use their PMS, then the Ministry will be able to obtain the influenza vaccine data for non-identifiable aggregate reporting. • General Practice and Pharmacy will continue to utilise their existing payment systems as the NIS is not linked to payments.
Service Delivery	• The influenza vaccination will be able to be administered in a range of setting: general practice, pharmacies, maraes, community vaccination centres. • Vaccine storage and distribution systems have been strengthened and the vaccinator workforce has been greatly expanded.

Implementation plan	
Infrastructure	• From 1 April 2022, all (publicly and privately funded influenza vaccinations) will be able to be recorded via a specific "form" in the National Immunisation Solution (NIS), which is the replacement for the National Immunisation Register. This is the first phase of the development of the NIS. • There is currently no legislative requirement for influenza vaccinations that are privately funded and privately provided to be entered into any national registry. Private providers would be encouraged to record influenza vaccinations in the NIS, but this may require some incentives such as funding or otherwise to support this.
Education, Training and Resources	• Tools and resources will be developed and available for providers to be used to used promote and deliver influenza immunisation programme effectively and safely. • Education and training will be available for those who will record influenza vaccination information into the NIS.
Quality, data and performance	• The Ministry will monitor the 2022 influenza immunisation programme performance. • Data requirements for reporting are being developed. This will enable a data driven approach to drive and enhance performance as experienced with the COVID -19 vaccination programme.

Appendix 4 – *Treasure Our Whānau* campaign poster example

MINISTRY OF HEALTH
MANATŪ HAUORA

Briefing

Lifting importation and use restrictions on unapproved COVID-19 vaccines

Date due to MO:	6 April 2022	**Action required by:**	11 April 2022
Security level:	IN CONFIDENCE	**Health Report number:**	HR20220551
To:	Hon Chris Hipkins, Minister for COVID-19 Response Hon Andrew Little, Minister of Health		
Copy to:	Rt Hon Jacinda Ardern, Prime Minister Hon Grant Robertson, Minister of Finance Hon Nanaia Mahuta, Minister of Foreign Affairs Hon Aupito William Sio, Associate Minister of Health Hon Dr Ayesha Verrall, Associate Minister of Health Hon Peeni Henare, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Dr Ashley Bloomfield	Director-General of Health	S9(2)(a)
Maree Roberts	Deputy Director-General, System Strategy and Policy	S9(2)(a)

Minister's office to complete:

☐ Approved	☐ Decline	☐ Noted
☐ Needs change	☐ Seen	☐ Overtaken by events
☐ See Minister's Notes	☐ Withdrawn	

Comment:

Lifting importation and use restrictions on unapproved COVID-19 vaccines

Security level:	IN CONFIDENCE	**Date:**	11 April 2022
To:	Hon Chris Hipkins, Minister for COVID-19 Response		

Purpose of report

1. This report:
   a. provides advice on the current controls in place to manage the importation and use of COVID-19 vaccines not approved for use in New Zealand
   b. seeks your agreement not to continue the current prohibition on the importation and use of unapproved COVID-19 vaccines.

Summary

2. Access to safe and effective vaccines through the COVID-19 immunisation programme (the Programme), alongside other public health measures, remains a core part of our COVID-19 response.

3. COVID-19 vaccines are defined as 'medicines' under the Medicines Act 1981 (the Medicines Act). While the Medicines Act requires medicines to be approved first before general supply, there are some exemptions which can lead to vaccines being imported without having undergone an approval process to demonstrate their safety, quality, and efficacy for use in New Zealand.

4. In early 2021, when global and domestic COVID-19 vaccine supply was constrained, the Ministry was notified of increasing interest by s 6(a) and the public to import and use unapproved vaccines in New Zealand. In April 2021, the Group Manager, Medsafe (under delegation from the Minister of Health) issued a Notice under section 37 of the Medicines Act to prohibit the importation and use of unapproved COVID-19 vaccines.

5. Over time, the national rollout of the COVID-19 immunisation programme and corresponding high rates of vaccine uptake, has reduced the interest in unapproved vaccines. There are also existing controls in the Medicines Act which officials consider will largely mitigate the current risk of the potential importation and use of unapproved vaccines.

6. The section 37 Notice expires on 27 April 2022, and officials recommend not extending the prohibition on the importation and use of unapproved COVID-19 vaccines.

We recommend you:

a) **Note** a Notice under section 37 of the Medicines Act is in force until 27 April 2022 to prohibit the importation, manufacture, packing, sale, possession, supply, administration or use of any vaccine for immunisation to prevent COVID-19.

b) **Note** the risks associated with unapproved vaccines and likelihood of their entry to New Zealand are low in the current context, given the mitigations under the Medicines Act 1981, restrictions on importers, and the successful rollout of the COVID-19 immunisation programme.

c) **Agree** not to extend the current prohibition on importing, manufacturing, packing, sale, possession, supply, administration or use of any vaccine for immunisation to prevent COVID-19. **Yes/No**

Hon Chris Hipkins

Minister for COVID-19 Response

10/4/22

Hon Andrew Little

Minister of Health

...../...../.....

Dr Ashley Bloomfield

Director-General of Health

5/4/22

Lifting importation and use restrictions on unapproved COVID-19 vaccines

Background

7. Access to safe and effective vaccines through the COVID-19 immunisation programme (the Programme), alongside other public health measures, remains a core part of our COVID-19 response.

8. COVID-19 vaccines purchased under our Vaccine Strategy [CAB-20-MIN-0229 refers] and administered through the COVID-19 Vaccine Immunisaton Programme (the Programme) have helped provide New Zealand's eligible population with protection against poor health outcomes from COVID-19. Every vaccine utilised in the Programme has been assessed by Medsafe for safety, quality, and efficacy prior to being made available.

9. In April 2021, the Ministry assessed the risks associated with the potential importation and use of COVID-19 vaccines not approved by Medsafe and purchased outside of the Vaccine Strategy as high. Subsequent action was taken to restrict importation of other COVID-19 vaccines to reduce this risk.

Existing regulation of COVID-19 vaccines and additional restrictions

All medicines require approval prior to use in New Zealand

10. Medsafe is the regulator of medicines and medical devices in New Zealand. It assesses the safety, efficacy and quality of medicines (including COVID-19 vaccines) before approving them, if appropriate for use in New Zealand. This process is comprehensive and follows international accepted guidance regarding the quality, safety, and effectiveness of medicines.

11. Companies wishing to supply a medicine in New Zealand must present extensive supporting information to demonstrate that its product is acceptable and meets all international standards and requirements under the Medicines Act. This prevents the New Zealand public from being exposed to poor quality, ineffective and counterfeit products.

12. There are exemptions under the Medicines Act which allow for the importation and use of unapproved medicines in limited circumstances. However, there are controls in the Medicines Act which apply to these exemptions. These controls reduce the risk of unsafe or low quality medicines being sourced outside of Medsafe approval and in this case, limit the likelihood of unapproved vaccines entering New Zealand. These controls include:

    a. limiting the importation and use of unapproved medicines by or for prescribers for administration to patients

    b. preventing the advertising of unapproved medicines to the public

    c. preventing the personal importation of unapproved medicines.

A section 37 Notice was introduced to completely prohibit the import, manufacture, packing, sale, possession, supply, administration or use of unapproved COVID-19 vaccines

13. In early 2021, when global and domestic COVID-19 vaccine supply was constrained, the Ministry was notified of increasing interest in the use of unapproved COVID-19 vaccines in New Zealand. The likelihood of importation and use by the public and s 6(a) s 6(a) n New Zealand was assessed as high.

14. Officials previously advised that despite the controls under the Medicines Act, there were considerable risks in allowing the importation and use of unapproved vaccines. The risks were outlined in advice to the Minister of Health [HR20210882], and are summarised below.

    a. **Safety risks:** COVID-19 vaccines not approved by Medsafe may expose people to poor quality, ineffective, unsafe and counterfeit products. Even if approved by other international regulators, they may not meet the safety assurance required for New Zealand. The import and use of unapproved vaccines may cause limited to no protection against COVID-19 and heightened risks of adverse events to unapproved vaccines.

    b. **Diversion of health resources:** to integrate unapproved vaccines into the Programme would negatively impact the roll out. This included the Programme's monitoring of recording of vaccinations, uptake, and national coverage. It would impact the safety training of practitioners and their rapid response to adverse vaccination events.

    c. **Other risks:** including risks to public confidence in the Programme, environmental concerns, and uncertainty on the liability for damages or injury. These concerns are detailed in the previous advice attached (see Appendix B).

15. The advice noted the existing regulatory controls were insufficient to ensure the safety or efficacy of vaccines sourced outside of Medsafe approval given the unprecedented demand for vaccines as a result of the pandemic [HR20210082 refers]. Certain benefits from the potential importation and use of unapproved medicines were recognised in previous advice, including the improved overall public and prescriber access to effective COVID-19 vaccines yet to be approved in New Zealand. However, on balance it was recommended that additional controls be implemented.

16. On 27 April 2021, a Notice was issued under section 37 of the Medicine Act to prohibit the importation, manufacture, packing, sale, possession, supply, administration or use of any vaccine for immunisation to prevent COVID-19 (see Appendix A).

17. The section 37 Notice can only be utilised once, for a specific time period not exceeding one year, and so will lapse on 27 April 2022. In order to extend the restrictions applied under the section 37 Notice, a section 11 Order under the COVID-19 Public Health Response Act 2020 would be required.

Proposal not to continue prohibition of COVID-19 vaccines

Officials are proposing that the Notice should be allowed to lapse with no extension to restrictions

18. The context around COVID-19 vaccines has changed and following the successful immunisation programme, demand for unapproved COVID-19 vaccines has reduced.

Officials consider that the controls in place without the section 37 Notice are sufficient to manage the potential risks in the current context.

The risk of importation of unapproved COVID-19 vaccines is much lower in 2022

19. The rollout of the Programme coordinated and directed a system wide response to meet public demand and need for COVID-19 vaccines. This has enabled a level of national immunisation coverage and protection against the impacts of COVID-19.

20. As a result, officials consider the likelihood of importation and use by the public to be much lower.

The current controls in place limit the remaining risks

21. As noted, the Medicines Act has provisions restricting the importation and use of unapproved medicines (including COVID-19 vaccines). The Act limits who can import and who can supply unapproved medicines. Organisations can only supply on the request of a medical practitioner for administration to a known patient under their care. Authorised prescribers can import for a patient under their care who is known to require the vaccine. In both instances, the Act limits importation or supply to health care professionals (either medical practitioners or authorised prescribers) who must ensure they provide healthcare of a professional standard and fully consider the risks and benefits of prescribing an unapproved vaccine.

22. The importation of COVID-19 vaccines is also very complex. The contractual and delivery requirements imposed by vaccine suppliers can be onerous. These include prerequisites for importation of meeting cost barriers, minimum dose delivery, cold chain management and complying with indemnity requirements.

23. Officials believe that in the current context, the provisions of the Medicines Act provide sufficient safeguards to manage the reduced demand for unapproved vaccines and their associated risks. Based on the this**, it is recommended that the current prohibition is not continued.**

Next steps

24. If you agree to our recommendation to not continue the prohibition on the importation, manufacture, packing, sale, possession, supply or use of COVID-19 vaccines then we will work with Medsafe and the Programme to manage the transition of the restriction and monitor for impacts on the vaccinations.

25. Officials note that the associated risks from the use of unapproved vaccines may change. The effectiveness of the above mitigations and constraints may change due to the evolving pandemic environment. Officials will continue to monitor the use of unapproved vaccines and advise whether a revised prohibition is required. If required, a future prohibition would likely be under a section 11 order under the COVID-19 Public Health and Response Act 2020.

ENDS.

Appendix A: Notice Under Section 37 of the Medicines Act 1981

Notice Under Section 37 of the Medicines Act 1981

Pursuant to section 37 of the Medicines Act 1981, the Minister of Health hereby prohibits the importation, manufacture, packing, sale, possession, supply, administration or use of any vaccine for immunisation to prevent coronavirus disease 2019 (COVID-19) caused by SARS-CoV-2 unless, in respect of a vaccine:

- the Minister of Health, or the Group Manager Medsafe (pursuant to delegation given by the Minister of Health) has given consent or provisional consent pursuant to sections 20 or 23 of the Medicines Act 1981; and
- the importation of the vaccine is made in accordance with all the conditions imposed by the Minister on giving consent or provisional consent and notified in the *New Zealand Gazette*.

The importation of the consented or provisional consented vaccine is, if relevant, subject to:

- the Director-General of Health, or the Group Manager Medsafe (pursuant to delegation given by the Minister of Health), giving their approval pursuant to section 24 of the Medicines Act 1981.

This notice does not apply to:

- a vaccine distributed for the purpose of obtaining clinical and scientific information with respect to its safety and efficacy approved pursuant to section 30 of the Medicines Act 1981.
- activities carried out by pharmacists in relation to packing, labelling and supply of the consented or provisional consented vaccine pursuant to section 26(1) of the Medicines Act 1981.
- a vaccine supplied in accordance with conditions that have been approved by the Group Manager, Medsafe, Ministry of Health under the Medicines Act 1981.

Note: This notice is valid for one year from the date of publication of this notice.

Dated this 27th day of April 2021.

DEREK FITZGERALD, Acting Group Manager, Ministry of Health (pursuant to delegation given by the Minister of Health on 11 September 2013).

Appendix B: HR20210882 - COVID-19 Vaccines – restricting importation and use outside the COVID-19 immunisation portfolio

MINISTRY OF HEALTH
MANATŪ HAUORA

Briefing

COVID-19 vaccines – restricting importation and use outside the COVID-19 Immunisation Programme

Date due to MO:	N/A	**Action required by:**	16 April 2021
Security level:	IN CONFIDENCE	**Health Report number:**	20210882
To:	Hon Andrew Little, Minister of Health		
Copy to:	Hon Chris Hipkins, Minister for COVID-19 Response Hon Ayesha Verrell, Associate Minister of Health		

Contact for telephone discussion

Name	Position	Telephone
Maree Roberts	Deputy Director-General System Strategy and Policy	s 9(2)(a) [redacted]
Therese Egan	Principal Policy Analyst Public Health System Policy	
Chris James	Group Manager Medsafe	

Minister's office to complete:

☐ Approved ☐ Decline ☐ Noted

☐ Needs change ☐ Seen ☐ Overtaken by events

☐ See Minister's Notes ☐ Withdrawn

Comment:

COVID-19 vaccines

Restricting importation and use outside the COVID-19 Immunisation Programme

Security level:	IN CONFIDENCE	**Date:**	14 April 2021
To:	Hon Andrew Little, Minister of Health		
Copy to:	Hon Chris Hipkins, Minister for COVID-19 Response Hon Ayesha Verrell, Associate Minister of Health		

Purpose of report

1. This report provides the Ministry's risk assessment of the importation and use of COVID-19 vaccines that have not been approved by Medsafe and purchased by the Ministry; and action proposed to be taken to prohibit this importation and use except in tightly defined circumstances.

Summary

2. The Ministry has assessed the risks associated with importation and use of COVID-19 vaccines outside Medsafe approval, outside Ministry purchase and outside the national COVID-19 Immunisation Programme.
3. The likelihood of such importation and use is high – almost certain for small groups in New Zealand and probable for larger groups such as certain migrant communities.
4. The risks are considerable to the health and safety of people in New Zealand, to the effectiveness of the Immunisation Programme and to New Zealand's global role in promoting equitable access to vaccines and recovery from the pandemic.
5. The most effective and enforceable action to restrict importation and use is via a Gazette Notice issued under section 37 of the Medicines Act 1981. The Group Manager Medsafe has delegated authority from the Minister of Health to issue this notice. Based on the Ministry's risk assessment, planning is underway for such a notice be issued during April 2021.
6. This report provides the Ministry's risk assessment, reasons for added regulatory restriction and choice of regulatory mechanism, and plans for communication and dealing with issues that may arise. It invites any feedback you wish to provide by 16 April 2021.

Recommendations

We recommend you:

a) **Note** the Ministry's assessment that restrictions on importation and use of COVID-19 vaccines, outside those approved by Medsafe and purchased by the Ministry of Health, are necessary to support:

- health and safety of people in New Zealand
- immunisation programme effectiveness
- New Zealand's contribution to pandemic recovery.

b) **Note** that, based on this assessment, the Group Manager Medsafe is planning to issue a Gazette notice under section 37 the Medicines Act 1981 prohibiting importation, manufacture, possession, advertising, packing, sale, supply or use of COVID-19 vaccines under sections 25 and 29 of the Act, for one year.

c) **Provide** any feedback by 16 April 2021

Yes / No

I support the proposed course of action.

Maree Roberts
Deputy Director-General
System Strategy and Policy
Date: 12 April 2021

Hon Andrew Little
Minister of Health
Date: 15/4/21

COVID-19 vaccines

Restricting importation and use outside the COVID-19 Immunisation Programme

Background / context

7. The Government is offering COVID-19 vaccination free of charge for all people who can safely receive it. A COVID-19 Immunisation Programme (the Programme) is underway to deliver vaccine sequentially in order to support the elimination strategy, lower the impacts of outbreaks and protect those most at risk.

8. Progress towards recovery from the impacts of COVID-19 requires that health system resources are directed to the most effective, equitable and safe delivery of vaccine while maintaining the pillars of the elimination strategy. The Programme is designed to achieve this for the New Zealand population, and to support the countries of Polynesia in their rollouts within the same time period.

9. Over 2021, the Programme will offer vaccine free of charge to all people in New Zealand (or Polynesia, via Polynesian governments) who can safely receive it. The Government has secured a portfolio of four COVID-19 vaccine candidates, each in quantities sufficient to vaccinate the people of New Zealand and Polynesia, subject to approval by Medsafe.

10. Rolling out the Programme will be the biggest ever immunisation effort in New Zealand. It will take highly coordinated and directed health system efforts to ensure safe delivery. In the midst of the pandemic, development of these vaccines has been driven by speed and effectiveness rather than ease of deployment. Strict transport, storage and vaccination conditions and active safety monitoring are requirements of their use.

11. Now, in the early stages of the Programme, most people will have to wait for vaccination. Medsafe has granted provisional consent for one vaccine (the Pfizer/BioNTech Comirnaty vaccine) to be used for people 16 years of age and over, and has received applications for three other vaccines. Limited quantities of vaccine are being delivered now for those at highest risk and the vaccinator workforce and Programme delivery capacity are building up.

12. From mid-year, the Programme will be rolled out to all people in New Zealand who are 16 years and over. Planning is underway for full population coverage by the end of 2021 (subject to logistical challenges and on-going risks). While this is a very fast rollout for such a large programme, inevitably there will be people who are waiting some months to be offered vaccination.

13. It is possible that some people in New Zealand will wish to "jump the queue" and receive vaccine before those deemed to be at higher risk, or to use an alternative vaccine product that they prefer for various reasons based on a range of information sources. This paper examines the risks associated with importing or using vaccines outside the Programme and without Medsafe approval. It presents the Ministry's assessment that additional regulatory controls are required.

Risks with vaccine use outside Medsafe approval and the Programme

Likelihood of importation and use of vaccines not approved by Medsafe

14. Vaccines are medicines under the Medicines Act 1981 (the Act). They are required to be approved by Medsafe in order to be imported, supplied, prescribed or administered. However, there are exception provisions in the Act that allow importation and use of an unapproved medicine by, or for, a medical practitioner for a particular (named) patient under that practitioner's care.

15. In general circumstances, these provisions (in sections 25 and 29 of the Act) allow for uncommon clinical needs to be met when there is not a suitable approved product available. This is not the case with COVID-19 vaccines. The Ministry has acquired a portfolio of vaccines and there is sufficient vaccine for all people in New Zealand.

16. However, unless further regulatory controls are implemented, these provisions are almost certain to be used to import and supply unapproved COVID-19 vaccines. There have already been several enquiries from Foreign missions and migrant communities about importing unapproved vaccines developed or used elsewhere in the world.

Human health and safety

17. Use of vaccines outside Medsafe approval raises safety risks. Vaccines that do not have regulatory approval for New Zealand's situation may expose people to harm through poor quality, ineffective, unsafe and counterfeit products, and increase their risks should they contract COVID-19. The components of an unapproved vaccine could be falsified and contain no active ingredient or be adulterated or of poor quality and contain a potentially harmful or counterfeit ingredient.

18. In the absence of Medsafe approval, even vaccines approved by other prominent international regulators may not meet the safety assurance required for a New Zealand context. Emergency use authorisations, given by many countries, are based on a higher risk tolerance than is applicable in New Zealand. Medsafe approval is based on its usual criteria and is specific to the manufacturing sites assessed. (Vaccines with the same branding but manufactured in different sites are not approved.)

19. Unapproved vaccines also lack New Zealand regulatory oversight and controls during their use. COVID-19 vaccines are for the most part novel vaccines to a novel virus, and the ability to take regulatory action based on post-market monitoring is very important. Regulatory action could include, for example, extending or tightening the population groups for whom use is approved, or cancelling approval and instituting recalls if a serious concern was to arise, whether in New Zealand or globally.

20. Similar concerns exist with using outside clinical restrictions (so-called "off-label prescribing") for population groups for whom there is no supporting safety evidence (such as children) or where there are increased safety risks. There may be instances where individuals at heightened risk of COVID-19 impacts should not be denied access to vaccine because of clinical restrictions and the Programme is designed to allow for such instances.

Diversion of health system resources

21. As the largest ever immunisation effort, the Programme will require a concentration of health system effort to ensure quality and a timely rollout.

22. Effective rollout of the Programme includes intensive monitoring of and adherence to vaccine conditions of use. These conditions rely on the data and digital infrastructure, workforce, facilities and service design approach set up around the vaccines being delivered. This includes monitoring of vaccine uptake, supporting optimal timing for follow-up to receive a second dose, and track and trace information. Such monitoring and responsiveness cannot easily or efficiently accommodate other vaccines from outside the Programme.

23. Advice for health practitioners and individuals about vaccination, including how it interfaces with many pre-existing clinical conditions, cannot easily be provided for vaccines not being used in the Programme. Fewer vaccines being used makes it easier for practitioners to develop expertise, including rapid responses to any health concerns that might arise. More vaccines being considered would add pressure and potential for confusion for busy health practitioners involved in a large and complex vaccine rollout.

24. Active monitoring for adverse events with causality assessment, investigation and response is a particularly important requirement for these relatively new vaccines and the added complexity of additional vaccines could be difficult, time-consuming and ineffective.

25. The use of unapproved products creates additional professional and ethical obligations for medical practitioners under the Code of Health and Disability Services Consumers' Rights. These include enhanced requirements for patients' informed consent and to undertake proportionate research into the unapproved product and alternatives. Because responsibility and liability for adverse effects lies with the prescriber, enhanced documentation of decisions and consultation is recommended.

Undermining public confidence in Programme equity and effectiveness

26. With short supply of vaccine and delivery capacity in the starting stages, public confidence in the Programme requires continued confidence in the overall elimination strategy (that New Zealand continues to be safe from COVID-19) and acceptance that sequencing is fair and offers the best overall protection for the community (that the people who most need protection will be protected).

27. Instances of "queue jumping" are likely to undermine overall public confidence in the Programme and the Government's ability to lead our pandemic response effectively and fairly.

Undermining New Zealand's global leadership for equitable vaccine access

28. Any private importation of vaccines to New Zealand would risk undermining confidence in our promotion of equitable global access to safe and effective vaccines. New Zealand has been a strong advocate of vaccine distribution throughout the world including in developing nations, and for governments to donate or share vaccine doses to achieve

maximal protection against COVID-19. Private markets are likely to increase competition for doses, rather than promote their effective deployment.

29. The presence in New Zealand of non-approved vaccines could also, by association with New Zealand's overall reputation, increase the risk of unsafe and ineffective vaccine use elsewhere and delay global pandemic recovery. Regional pandemic recovery may be at particular risk as Pacific countries may be a geostrategic destination for donated vaccines.

Environmental risks

30. Certain COVID-19 vaccines in development around the world may be based on new biological organisms or material. Environmental Protection Authority review may be required prior to importation of vaccines that may contain hazardous substances and new organisms. This review may be missed without Medsafe's scrutiny.

31. Safe waste management and disposal of vaccines is required for safety of human health and the environment, whether or not hazardous substances or new organisms are involved. Good practice in waste management is built into the Ministry's purchase and management plans but may be lacking unregulated imports.

Liability for any injury or damages

32. COVID-19 vaccine suppliers in general are requiring those using their vaccines to indemnify them, in view of their rapid development of products during the pandemic. The New Zealand Government has provided this indemnity for suppliers of vaccines purchased by the Ministry of Health and approved by Medsafe. People in New Zealand have access to compensation and health care for any injury that might potentially occur.

33. Liability for any injury or damages to persons or the environment from unapproved vaccines is unclear.

Risk mitigation

34. Strong communication is key to reducing risks, focused on free vaccine for all, the benefits of vaccine being given first to those at high risk, and the ongoing importance of our elimination strategy.

35. Free access to vaccine for everyone in New Zealand will reduce, but not eliminate, demand for private importation. Cabinet has agreed to expand eligibility for publicly funded COVID-19 immunisation to everyone in New Zealand, regardless of immigration status. Some 270,000 people not generally eligible for publicly funded health services will be offered free COVID-19 vaccination. This includes temporary visitors, workers under the Recognised Seasonal Employers (RSE) scheme, diplomatic and consular staff from other countries, and people in New Zealand unlawfully.

36. Strong communication for all communities, stressing the importance of pulling together to support the team of 5 million, will reduce anxiety and promote confidence in the Programme and in New Zealand's overall response to COVID-19. Communication supports widespread understanding of the benefits of the Programme with its sequencing approach and the continued importance of public health measures and the elimination strategy.

37. In particular, information and support for health practitioners will increase the trusted information and support available to the public.

Requirement for additional regulatory controls

Current regulatory controls

38. Medsafe, as the New Zealand medicines and medical devices regulator, assesses the safety, efficacy and quality of medicines (including vaccines) before approving them, if appropriate, for use in New Zealand under the Medicines Act 1981. This Act provides for the regulation, classification and permissions for distribution and use of medicines, including vaccines, in New Zealand. The Medicines Act allows for the importation and use of unapproved medicines in New Zealand; importation by or for prescribers for administration to particular patients is permitted, and in general circumstances allows for uncommon clinical needs to be met when there is not a suitable approved product available.

39. The current regulatory controls are not sufficient to ensure the safety or efficacy of vaccines sourced outside of Medsafe approval. This is particularly true given the current unprecedented demand for vaccines globally, including in New Zealand.

Additional regulatory control options

40. Two options exist for additional regulatory controls – a Medicines Act notice (time limited) or a COVID Act order (less easily enforced).

41. Section 37 of the Medicines Act allows the Minister of Health to issue a notice prohibiting the import, manufacture, packing, sale, possession, supply, administration, or other use of medicines or medical devices of any specified description. The Minister of Health has delegated this responsibility to the Group Manager, Medsafe. The issuance of section 37 notices is rare, and the practice has been to proceed after there is policy agreement that the additional regulatory control is required.

42. A section 37 notice could be drafted to prohibit the importation manufacture, possession, advertising, packing, sale, supply or use of COVID-19 vaccines unless they are approved by Medsafe and imported by the Ministry of Health. This would would contribute to increasing uptake and efficient delivery of vaccines offered through the Programme and to lowering the risks that could lower compliance with public health measures to prevent spread of COVID-19.

43. The section 37 provision was exercised successfully in April 2020 to prevent the importation, manufacture, packing, sale, supply or use of any kits and/or other test materials intended for use as point-of-care testing for COVID-19 infection, or for post-infection confirmation, using an antigen or antibody detection system. The powers in the Medicines Act are substantial to deter, detect, enforce and prosecute offences. Communication routes for prescribers, suppliers and other key parties are well established.

44. However, the section 37 provision can only be utilised once, for a specified time period not exceeding one year. A section 11 order under the COVID-19 Public Health Response Act 2020 (COVID Act order) was required for test kits when the 12-month period expired and continued prohibitions were needed.

45. A COVID Act order contributes to preventing the risk of outbreak or spread of COVID-19 by requiring people to take, comply with or refrain from actions, activities or measures. A COVID Act order could be used to effect the same prohibitions and exceptions available through a Medicines Act notice. While a Medicines Act notice is preferred at this time because of its specificity and wellestablished powers, processes and communication systems, a section 11 order could be used in future should a longer timeframe be required.

Specific exceptions to the recommended prohibition

46. Specific exceptions to prohibition will be few and, we anticipate, able to be tightly managed through existing processes (eg, for research) or through Programme design and management (eg, for unusual clinical indications).

47. Clinical trials of vaccines would remain permitted and subject to Medsafe approval, on the recommendation of the Health Research Council of New Zealand, under section 30 of the Medicines Act.

48. There may be rare clinical situations where a certain vaccine delivered through the Programme cannot be used. The recommended approach will be for another vaccine that is available to the Programme to be considered, where applicable. (It is likely that, in the coming months, other vaccines the Government has purchased in advance may be approved by Medsafe and available to the Programme.)

Foreign Missions in New Zealand

49. Foreign missions in New Zealand have welcomed the New Zealand government's decision to make local vaccine available to everyone in New Zealand free of charge. Access for foreign diplomatic, consular, and official personnel and their family members to vaccine under New Zealand's roll-out is appreciated. A number of missions have also noted this takes some pressure off them in respect of their own expatriate communities in New Zealand.

50. However, a few foreign missions have also enquired about their ability to directly import vaccines. Some have sought this ability for all of their staff, others primarily for staff scheduled to depart New Zealand to take up their next assignment in a high COVID risk environment. Exceptions now allow foreign mission staff and family members of diplomatic, consular and official personnel to receive early vaccination where they are required to travel before the end of August on compassionate grounds or for reasons of national significance.

51. The Ministry of Foreign Affairs and Trade (MFAT) is providing information to foreign missions on New Zealand's vaccine planning and key developments relating to the roll-out. MFAT will mirror the Ministry of Health's broader communications, encouraging acceptance of vaccinations under New Zealand's roll-out, in communications with the diplomatic corps.

52. If a notice is issued to prohibit import of vaccine outside the Programme, MFAT will communicate this to foreign missions (who have a duty to respect the law and regulations of New Zealand). While vaccine could be imported without our knowledge (diplomats, diplomatic premises and diplomatic shipments are inviolable), it is unlikely foreign missions would seek to import with this regulatory change, especially given accessibility of New

Zealand's Programme to their staff, including to those required to travel to countries with high COVID-19 risk.

Equity

53. The Ministry's risk assessment has considered equity of outcomes in New Zealand, as promoted through the Immunisation Programme and sequencing framework. Deviation from the Immunisation Programme may have a negative effect on equity of protection from the impacts of COVID-19 afforded by vaccination by diverting health system resource and attention. In the same way, it may impact equity of recovery from COVID-19 across communities in New Zealand and in our neighbouring Pacific countries.

54. The risk assessment has also considered global equity through access to vaccination and recovery from the pandemic. New Zealand has played an influential role in supporting the World Health Organization and Gavi, the vaccines alliance, in promoting equitable access to vaccines. This work continues, such as in working towards a mechanism whereby countries can share vaccine doses through the COVAX Facility.

Next steps

55. Medsafe is drafting a section 37 Gazette Notice that would prohibit importation, manufacture, possession, advertising, packing, sale, supply or use of COVID-19 vaccines under sections 25 and 29 of the Act, for one year. In line with any feedback you provide on this report, such a notice would be issued together with associated communications for suppliers, prescribers and practitioners.

56. The Ministry will continue to update communications for the public, health practitioners and particular communities that emphasise the benefits for the whole community of the Government's COVID-19 Immunisation Programme and continued adherence to public health advice.

57. The Ministry will continue to work with the Ministry of Foreign Affairs and Trade to ensure foreign diplomatic missions are fully informed of the vaccination availability for their staff and citizens present in New Zealand.

ENDS.