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11 November 2021

Sebastian

By email: fyi-request-16691-fd5eef19@requests.fyi.org.nz

Ref: H202115494

Tēnā koe Sebastian

#### Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) to the Ministry of Health (the Ministry) on 4 November 2021 for:

.."...all COVID-19 Vaccine Technical Advisory Group meeting minutes, dated since the 6 October."

Two documents have been identified within scope of your request. The documents are itemised in Appendix 1. The table in Appendix 1 outlines the grounds under which I have decided to withhold information. Where information is withheld, this is noted in the document itself.

Under section 28(3) of the Act, you have the right to ask the Ombudsman to review any decisions made under this request. The Ombudsman may be contacted by email at: <a href="mailto:info@ombudsman.parliament.nz">info@ombudsman.parliament.nz</a> or by calling 0800 802 602.

Please note that this response, with your personal details removed, may be published on the Ministry website at: <a href="https://www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests">www.health.govt.nz/about-ministry/information-releases/responses-official-information-act-requests</a>.

Nāku noa, nā

Professor Ian Town

**Chief Science Advisor** 

**COVID-19 Technical Advisory Group** 

## Appendix 1: List of documents

#	Date	Title	Decision on release
1	19 October 2021	Minutes: COVID-19 Vaccine Technical Advisory Group	Some information withheld under section 9(2)(k) of the Act, to prevent the disclosure or use of official information for improper gain or improper advantage.
2	2 November 2021		



# **MINUTES: COVID-19 Vaccine Technical Advisory Group**

Date:	e: Tuesday 19 October 2021		
Time:		11:00am to 12:00pm	
Locatio	n:	s 9(2)(k)	
Chair:		lan Town	
Membe	rs:	David Murdoch, Elizabeth Wilson, Helen Petousis-Harris, James Ussher, Nikki Moreland, Peter McIntyre, Sean Hanna,	
Ministry	y of Health Attendees:	Andi Shirtcliffe, Brooke Hollingshead, Chriselle Braganza, Edwin Reynolds, Erin Smith, Fiona Callaghan, Juliet Rumball-Smith, Pippa Scott	
Guests:	:	Chris James, John Tait, Kris Golding, Susan Kenyon, Ralph Stewart	
Apologi	ies:	Caroline McElnay, Daniel Bernal, Ian Frazer, Niki Stefanogiannis, Nikki Turner, Sue Crengle, Tony Walls,	
1.0	Welcome and previous minutes  Ian Town welcomed all Members and Attendees in his capacity as Chair of the COVID-19 Vaccine Technical Advisory Group (CV TAG).  Minutes of the last meeting (05 October 2021) were accepted.		
2.0	Vaccine Rollout and Outbreak  The Chair provided an update on the vaccine rollout:  • 'Super Saturday' on October 16 provided a major boost to the vaccination rollout with approximately 130,000 doses administered, and many doses were among Māori and younger adults. All data broken down by DHB is publicly available on the Ministry of Health website.		
3.0	<ul> <li>The evidence brief that CV TAG provided input into to support the mandatory vaccination of healthcare workers is being finalised. A brief evidence summary was included with the Cab paper, focussing on the effect of vaccination on transmission.</li> <li>The specifics of any exemption policy were discussed. A small group of people may be me exempt from the Pfizer vaccine, however, having an alternative vaccine available may also interest to other groups eg, healthcare workers.</li> </ul>		
4.0	The AstraZeneo vaccine due to o	d evidence brief from CV TAG will be signed out as a memo and shared with CVIP.  straZeneca eneca vaccine may be considered for people who are unable to take the Pfizer to contraindications, or due to issues with their first dose, as well as those hesitant g an mRNA vaccine.	

- The vaccine was considered suitable for anyone eligible and indicated as per the Medsafe data sheet, however it was noted that the data sheet had no age restrictions in its indication, nor prescribed dosing intervals.
- AstraZeneca has been used with a range of dosing intervals (e.g., 4-12 weeks), though some countries have reduced this to four weeks in an outbreak.
- The risk of thrombosis and thrombosis with thrombocytopaenia was noted as a concern, with
  incident rates higher among younger adults. AusVaxSafety provide comparative data by age for
  AstraZeneca and Pfizer and would be a useful resource. It was also noted that the vaccine has
  not been trialled or used among pregnant people.
- Possible distribution channels for the different groups were queried. Distribution will likely be
  limited to certain centres to reduce the risk of error and due to larger volumes of the vaccine
  being needed to avoid waste. Those who had had an adverse event after their first dose could be
  referred through primarycare. People with a preference for a non-mRNA vaccine could be
  directed to certain vaccine centres with supplies or receive a booking code.
- The STA team will draft recommendations for CV TAG to consider this week based on the Medsafe data sheet and data internationally.
- The Ministry of Health's Policy team may seek advice on Janssen, Novavax or AstraZeneca at a later date.

#### 5.0 Myocarditis Update

- An update was provided from STA on the risk of myocarditis according to international evidence.
  Data presented at the latest US ACIP meeting on 30 August 2021 and data from Israel indicate
  that myocarditis reporting rates following mRNA COVID-19 vaccination continue to be rare
  overall, but highest risk tends to occur after the second dose, particularly in younger males.
- Medsafe also shared the latest data on cases. The safety profile differs to the US in that New Zealand is seeing more cases after dose 1 than dose 2, however this could reflect the vaccine rollout with more young people being vaccinated later. Onset tends to be reported in the first five days for both dose. Data on dosing intervals has not been analysed, however it has been noted that cases have still occurred at an interval of 6-8 weeks. Overall, the rate is approximately 7 per million doses after dose 1, and 10 per million doses after dose 2. Peopled aged 30-39 are the most affected age group in New Zealand overall, and after dose 1, and people aged 20-29 are most affected after dose 2. Long-term follow-up data is expected by end of November.
- ISMB shared that levels of reporting seem to correlate with the numbers of reports being received, looking at the number of hospitalisations in vaccinated individuals. Every case reported to CARM is reviewed by a medical assessor, and when there is insufficient data, further information is requested. If there is a risk of death, biopsies and post-mortems of myocardiums are requested. No long-term outcome data is currently available.
- Information on symptoms to watch out for have been provided to all vaccinators, however it is possible that some centres are still using older booklets from before the advice was given.
- Milder cases may benefit from further clinical investigation, and greater standardisation in management of care may be needed with ECGs and provision of troponins. Accessiblity of the guidance for general practice and primary care will be reviewed.
- As previously noted, people who have myocarditis after their first dose should not be offered a second dose of an mRNA vaccine, and an alternative vaccine or no further doses should be considered for those people.
- No further evidence had emerged that decreasing the dose interval had impacted myocarditis.
- A clinical research project is one option to consider looking at myocarditis in greater detail.

#### 6.0 Decision to Use 5–11-Year-Olds

- Medsafe are expecting an application from Pfizer in mid-November. The US FDA are reviewing data for 5-11-year-olds at the end of October.
- Little information has been provided on the paediatric formulation which Pfizer are currently trialling, however it may be of importance.
- STA will convene a subgroup of CV TAG to discuss priority groups and equity considerations for recommendations and a Decision to Use.
- Whether the 5–11-year-olds and 12–15-year-olds who are of lower weight may need a lower dose was discussed. Medsafe are reviewing whether any dose ranging studies were included in Pfizer's initial application.

#### 7.0 Next Steps/Decisions Pending

None.

#### 8.0 Any Other Business

Booster doses

- Medsafe are expecting an application from Pfizer for booster doses by the end of October.
- It was noted that there is significant demand for booster doses among healthcare workers, especially those in Auckland who perceive a safety issue having been vaccinated early on.
- The STA team are drafting recommendations on priority groups for CV TAG's consideration.
- A medium and longer strategic term lens looking to periods of greatest risk and demand in 2022 will be factored into the recommendations.
- Details of a third primary doses for immunocompromised people with a suboptimal immune response have been accepted by CVIP and will be announced.

#### 9.0 Agenda items for next meeting

VAANZ Ka Mātau, Ka Ora study

 An extended protocol has been submitted to do additional immunology work, and a further funding request has been submitted, which will need to come through CV TAG.

#### 10.0 New Action Items Raised During Meeting

	#	Agenda item	Actions	Action Owner
2	64	Supporting Evidence for Healthcare Worker Vaccination Order	Finalise evidence brief and share with CVIP and CV TAG	Science and Technical Advisory
	65	Decision to Use AstraZeneca	Draft recommendations for a Decision to Use memo shared with CV TAG	Science and Technical Advisory
	66	Myocarditis	Discuss clinical guidance for primary care with CVIP	Science and Technical Advisory
	67	Myocarditis	Convene subTAG to consider research	Science and Technical Advisory

68	Decision to Use 5–11-Year- Olds	Convene subgroup to compile evidence and discuss equity considerations	Science and Technical Advisory
69	Decision to Use 5–11-Year- Olds	Review Pfizer's application for 12-to- 15-year-olds for evidence on dosages.	Medsafe
70	Booster doses	Draft recommendations shared with CV TAG	Science and Technical Advisory

Meeting closed at 12:11pm

Next meeting: Tuesday 02 November – 11:00am to 12:00pm

### **Open Actions:**

#	Agenda item	Actions	Action Owner	Updates
49	Pfizer dosing error	Compile further evidence on the link between dosing intervals and reactogenicity.	Science and Technical Advisory	31/08 – Action raised
60	Booster doses	Compile evidence on need for booster doses	Science and Technical Advisory	21/09 – Action raised
64	Supporting Evidence for Healthcare Worker Vaccination Order	Finalise evidence brief and share with CVIP and CV TAG	Science and Technical Advisory	19/10 – Action raised
65	Decision to Use AstraZeneca	Draft recommendations for a  Decision to Use memo shared with CV TAG	Science and Technical Advisory	19/10 – Action raised
66	Myocarditis	Convene subgroup to update clinical guidance for primary care	Science and Technical Advisory	19/10 – Action raised
67	Decision to Use 5– 11-Year-Olds	Convene subgroup to compile evidence and discuss equity considerations	Science and Technical Advisory	19/10 – Action raised
68	Decision to Use 5– 11-Year-Olds	Review Pfizer's application for 12-to-15-year olds for evidence on dosages.	Medsafe	19/10 – Action raised
69	Booster doses	Draft recommendations shared with CV TAG	Science and Technical Advisory	19/10 – Action raised

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## **Closed Actions Since Last Meeting:**

#	Agenda item	Actions	Action Owner	Updates
59	Vaccines recognised for arrivals	Request data on positivity rates from MIQ testing requirements	Science and Technical Advisory	21/09 – Action raised 08/10 - Action closed
63	Vaccines recognised for MIQ entry and RSE workers	Share finalised memos with CV TAG	Secretariat	5/10 – Action raised 08/10 - Action closed



# **MINUTES: COVID-19 Vaccine Technical Advisory Group**

Date:	te: Tuesday 02 November 2021		
Time:		11:00am to 12:00pm	
Locatio	n:	9(2)(k)	
Chair:		lan Town	
Membe	rs:	Elizabeth Wilson, Helen Petousis-Harris, Ian Frazer, James Ussher, Nikki Moreland, Nikki Turner, Peter McIntyre, Sue Crengle, Tony Walls	
Ministry	y of Health Attendees:	Brooke Hollingshead, Chriselle Braganza, Daniel Bernal, Edwin Reynolds, Erin Smith, Fiona Callaghan, Juliet Rumball-Smith, Pippa Scott	
Guests	:	John Tait, Kris Golding, Thomas Teunissen, Liam McConnell	
Apolog	ies:	David Murdoch, Sean Hanna, Andi Shirtcliffe, Caroline McElnay, Niki Stefanogiannis	
2.0	Ian Town welcomed all Members and Attendees in his capacity as Chair of the COVID-19 Vaccine Technical Advisory Group (CV TAG).  Minutes of the last meeting (19 October 2021) were accepted.  Vaccine Rollout and Outbreak  Vaccine uptake continues to increase. Vaccination rollout data and case details are available the Ministry of Health website.		
3.0	<ul> <li>Decision to Use AstraZeneca</li> <li>The finalised recommendations have been shared with the Director-General and CVIP team is now working on acquiring doses of the AstraZeneca vaccine. As recommended TAG, this vaccine will be targeted to those who are contraindicated to the Pfizer vaccine hesitant about receiving an mRNA vaccine.</li> <li>Details of implementation will be brought back to CV TAG to outline delivery dates and be operationalised.</li> <li>Doses of the Janssen vaccine are still expected in early 2022.</li> </ul>		
4.0	4.0 Medical exemptions		
	Draft recommendations discussed.	on the clinical criteria for temporary medical exemptions to the vaccine were	
		dations were drafted based on ATAGI advice, and are intended to be temporary ting for a maximum of six months.	

- The recommendations limit medical exemptions to a narrow group of people including: people who have had anaphylaxis to the first dose, inflammatory cardiac illness, PCR-confirmed infection, a serious adverse event to prior dose, or for people who are unable to tolerate vaccination (e.g. people with severe neurodevelopment conditions).
- Once alternative vaccine(s) are available, there will be changes to the exemptions, and it will be
  important to ensure that alternative vaccines are suitable e.g., the AstraZeneca 's TTS risk in
  younger age groups should be considered.
- A temporary exemption should be included for people who experience myocarditis after the first dose.
- A temporary exemption will be offered for people who are in clinical trials, e.g., the Valneva clinical trial. Reasons for this include not placing an undue burden on clinical trial participants and being unable to retrospectively impose conditions on trial participants that they have not agreed to.
- Discussion occurred on who would have the ability to grant medical exemptions, and further guidance will be sought from IMAC and the Ministry's Clinical Quality and Safety team.
- The draft memo will be revised and finalised.

#### 5.0 Booster doses

Draft recommendations on the clinical criteria for booster doses were discussed.

- These were based on the JCVI and ATAGI advice and New Zealand's original prioritisation framework.
- CV TAG requested that the criteria be simplified, and the prioritisation framework not be used, due
  to New Zealand being in a different context with circulating virus, ample vaccine supply and
  infrastructure to deliver booster doses.
- Boosters for everyone over 30 were discussed with access to a booster dose at least 6 months
  after their primary course of vaccination, however there is insufficient data on the risk and safety
  for younger people at this stage.
- Prioritisation for people at high risk of severe disease (e.g., Māori), and high risk of exposure (e.g., healthcare workers), followed by their whānau was discussed.
- Age-criteria for prioritisations raise equity concerns particularly for Māori due to the increased risk
  of severe disease and hospitalisation, i.e., a lower age band for Māori should be considered to
  provide equivalent protection.
- Concern was expressed that this would divert efforts and attention away from primary vaccination
  efforts, and therefore first and second doses should be prioritised over booster doses, and an
  overarching statement will be added to the recommendations to this effect.
- The memo will be updated with the feedback from CV TAG and shared with CVIP once Medsafe approval occurs.

#### 6.0 'Fully-vaccinated' definition

- Draft recommendations on the criteria for 'fully-vaccinated' within the New Zealand border were shared, with this defined as being 7 days after a complete course of a COVID vaccine.
- This would be used for vaccine certificates and in areas where vaccines are mandated within New Zealand's borders, and is not related to work on which vaccines would be recognised at New Zealand's border.
- Which vaccines will be included under these guidelines (e.g., WHO recognised vaccines vs. vaccines recognised by a Medsafe Recognised Authority) was discussed, and which vaccines may benefit from an additional dose.

- Heterologous schedules were seen as generally acceptable.
- There was discussion about the risks of mandating vaccinations for people at elevated risk of adverse events e.g., younger people aged 12-17 and the increased risk of myocarditis after the second dose, and a single dose may be sufficient
- There was also some discussion about whether younger people with a documented infection may only need one dose.
- A finalised version of the memo will be distributed.

#### 7.0 Immunocompromised populations and ATAGI's update guidance

- CV TAG issued guidelines on which immunocompromised populations should be considered for a
  third primary dose in September. Since then, ATAGI have updated their guidance to include some
  broader groupings, and the Ministry received some feedback from rheumatology and haematology
  groups.
- The timing for the third primary dose will also be updated to be from 4 weeks, rather than 8 weeks, as some flexibility is needed in relation to the timing of treatment.
- Guidance will be updated to reflect this feedback.

#### 8.1 Research Studies: VAANZ further funding request

A proposal to extended funding for the Ka Mātau, Ka Ora Study was considered by CV TAG.

- The Ka Mātau, Ka Ora Study is assessing immunogenicity of the Pfizer vaccine in New Zealand recipients >=16 years old and comparing immune responses by age, ethnicity and presence of comorbidities.
- The research was seen to be of great importance to understanding differences in immune responses for the Ministry of Health, with funding being drawn from the Ministry's Post-Event research funding pool.
- The extension of funding was supported.

#### 8.2 Research Studies: Myocarditis research

A request to support research myocarditis following COVID-19 vaccination was also considered.

- An ongoing long-term follow-up study was discussed regarding cases with a clinical diagnosis of myocarditis and/or pericarditis following vaccination, as reported to CARM.
- CV TAG members were requested to volunteer to form a subgroup to develop plans and present a
  proposal for additional research questions to the Post-Event team.

# 8.3 Research extension: Establishing a foundation for monitoring the safety of COVID-19 vaccines using primary care data

A request to endorse an extension of a research project from the University of Auckland (UoA) was received.

- The extension will allow the project to establish background rates of adverse events of special interest (AESI) of COVID-19 vaccines from hospital discharge data and enable a foundation for monitoring the safety of COVID-19 vaccines using primary care data.
- CV TAG noted that having baseline rates would be valuable to determine the safety profile of vaccines and endorsed the proposal.

#### 9.0 Medsafe provisional approval of the Pfizer vaccine extended

	Document 2
	It was noted that Medsafe provisional approval has been extended for a further two years, until November
	2023.
10.0	Medsafe Safety Report 33
	The latest Medsafe Safety Report was shared with CV TAG for noting and will be published publicly soon,
	with it giving a line of sight to reported adverse events.

### 11.0 Next Steps/Decisions Pending

None.

#### 12.0 Any Other Business

Decision to Use for 5-11-year-olds

- An initial discussion occurred on the Pfizer vaccine for 5–11-year-olds.
- The recent clinical trial occurred among a relatively small sample of ~2000 children. Rare adverse events cannot be evaluated in a clinical trial of that size. New Zealand would be able to wait for the real-world data of the vaccine rollout internationally to evaluated safety and effectiveness.
- The benefit:risk ratio was not as obvious for this group as for older populations, as COVID-19
  presents as a mild disease in this age group and there appears to be an increased risk of
  myocarditis after vaccination in younger age groups.
- Concern was also expressed on including 5–11-year-olds under vaccine certificates and mandates, with potential effects on education and wellbeing.
- However, different risks for Māori and 5-11-year-olds vulnerable to severe COVID-19 or immunocompromise should be considered
- A subgroup of CV TAG will be meeting to draft recommendations in the coming days.

#### 13.0 Agenda items for next meeting

Booster doses

Decision to use for 5-11-year-olds

#### 14.0 New Action Items Raised During Meeting

#	Agenda item	Actions	Action Owner
70	Medical exemptions	Revise memo with CV TAG's feedback and share with CVIP	Science and Technical Advisory
71	Booster doses	Revise memo with CV TAG's feedback	Science and Technical Advisory
72	'Fully vaccinated' definition	Revise memo with CV TAG's feedback	Science and Technical Advisory
73	Immunocompromised populations and ATAGI's update guidance	Revise memo with CV TAG's feedback and share with CVIP	Science and Technical Advisory

Meeting closed at 12:01pm

Next meeting: Tuesday 9 November - 11:00am to 12:00pm

## **Open Actions:**

#	Agenda item	Actions	Action Owner	Updates
49	Pfizer dosing error	Compile further evidence on the link between dosing intervals and reactogenicity.	Science and Technical Advisory	31/08 – Action raised
64	Supporting Evidence for Healthcare Worker Vaccination Order	Finalise evidence brief and share with CVIP and CV TAG	Science and Technical Advisory	19/10 – Action raised
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70	Medical exemptions	Revise memo with CV TAG's feedback and share with CVIP	Science and Technical Advisory	02/11 – Action raised
71	Booster doses	Revise memo with CV TAG's feedback	Science and Technical Advisory	02/11 – Action raised
72	'Fully vaccinated' definition	Revise memo with CV TAG's feedback	Science and Technical Advisory	02/11 – Action raised
73	Immunocompromised populations and ATAGI's update guidance	Revise memo with CV TAG's feedback and share with CVIP	Science and Technical Advisory	02/11 – Action raised

# **Closed Actions Since Last Meeting:**

#	Agenda item	Actions	Action Owner	Updates
60	Booster doses	Compile evidence on need for booster doses	Science and Technical Advisory	21/09 – Action raised 01/11 – Action closed

65	Decision to Use AstraZeneca	Draft recommendations for a Decision to Use memo shared with CV TAG	Science and Technical Advisory	19/10 – Action raised 29/10 – Action closed
69	Booster doses	Draft recommendations shared with CV TAG	Science and Technical Advisory	19/10 – Action raised 01/11 – Action closed

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