133 Molesworth Street
PO Box 5013
Wellington 6140
New Zealand
T+64 4 496 2000

21 January 2022

s 9(2)(a) [redacted]

[redacted] [redacted]

Ref: H202116357

Tēnā koe s 9(2)(a) [redacted]

Response to your request for official information

Thank you for your request under the Official Information Act 1982 (the Act) which was transferred from the Department of the Prime Minister and Cabinet to the Ministry of Health (the Ministry) on 16 November 2021 for information regarding the COVID-19 vaccine.
On 24 November 2021, you were advised through email correspondence that your request was for a large volume of information and may be refused under section 18(f) of the Act. You were asked to provide a refinement. On 24 November 2021, you refined your request to only include information from July and August 2021. Please find a response to each part of your refined request below:

> *"I would like to make a formal request for all meeting minutes, notes and correspondence made by the COVID-19 Technical Advisory Group from January 2021 to the latest date, in relation to and pertaining to all information and research used which enabled the COVID-19 Technical Advisory Group to conclude why 12–15-year-olds should receive 2 doses of the Comirnaty Pfizer-BioNTech covid-19 vaccinations in New Zealand?*
>
> *In addition I would like to make a formal request for all meeting minutes, notes and correspondence made by the COVID-19 Technical Advisory Group in relation to and pertaining to where they sent said information, advise and recommendations?*

Administering the COVID-19 vaccine as a single dose for younger people was discussed and considered by the COVID-19 Vaccine Technical Advisory Group (CV TAG). Information within scope has been provided in excerpts in accordance with section 16(e) of the Act and attached as *Document 1*. The Ministry has also identified two additional CV TAG memos within scope of these parts of your request. All documents have been itemised in Appendix 1 to this letter, and copies of the documents are enclosed. Please note that recommendation 12(c) from the 12-5 Priority Group memo is what drove the subsequent approach as part of the Delta outbreak management. New Zealand went into lockdown because of the outbreak and vaccination of the 12-15 group became an important strategy in mitigating the spread of the virus between families and communities. Please also note that the Comirnaty COVID-19 vaccine was approved by Medsafe as a two-dose vaccine. Further information on the approval of the vaccine for those aged twelve and older, along with current indications, can be found on the datasheet on the Medsafe website at: www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf.

In addition I would like to make a formal request for the official URL website address of the COVID-19 Technical Advisory Group? Note not the list of members as per the government website. I am requesting the official URL website address of the COVID-19 Technical Advisory Group?

The CV TAG does not have a website. As such, the requested information is refused under section 18(e) of the Act as the information does not exist.

I would like to make a formal request for all meeting minutes, notes and correspondence, in writing or verbally transcribed, made by Medicines Assessment Advisory Committee from January 2021 to the most recent date, in relation to and pertaining to all information and research used which enabled Medicines Assessment Advisory Committee to conclude why 12-15 year olds should receive 2 doses of the Comirnaty Pfizer-BioNTech covid-19 vaccinations in New Zealand?

In addition I would like to make a formal request for all meeting minutes, notes and correspondence, in writing or verbally transcribed, made by Medicines Assessment Advisory Committee in relation to and pertaining to where they sent the above said information, advise and recommendations?

In addition I would like to make a formal request to receive a list of the members/persons who attend above said meetings relating to the discussions of Comirnaty Pfizer/BioNTech COVID-19 vaccine in relation to 12-15 year olds.

A change medicine notification to extend the indication to adolescents 12 to 15 years of age was gazetted on 21 June 2021, subject to section 23(1) of the Medicines Act 1981. It was not necessary to refer this application to the Medicines Assessment Advisors Group (MAAC). As such, the information requested in these parts of your request is refused under section 18(e) of the Act, as the information does not exist. Information about the Medsafe approval process can be found at: www.medsafe.govt.nz/COVID-19/vaccine-approval-process.asp.

I would like to make a formal request for all meeting minutes, notes and correspondence, in writing or verbally transcribed, made by Medsafe from January 2021 to the most recent date, in relation to and pertaining to all information and research Including but not limited to Medsafe assessment reports, and all information which enabled Medsafe to conclude why 12–15-year-olds should receive 2 doses of the Comirnaty Pfizer-BioNTech covid-19 vaccinations in New Zealand?

The Ministry does not hold information within scope of this part of your request. As such, this part of your request is refused under section 18(g) of the Act, as the information is not held by the Ministry, and there are no grounds for believing it is held by any other agency subject to the Act.

In addition, I would like to make a formal request for all meeting minutes, notes and correspondence, in writing or verbally transcribed, made by Medsafe in relation to and pertaining to where they sent the above said information, advise and recommendations?

In addition, I would like to make a formal request to receive a list of the members/persons who attend above said meetings relating to the discussions of Comirnaty Pfizer/BioNTech COVID-19 vaccine in relation to 12-15 year olds"

The information in these part relates to sending information to MAAC. As above, it was not necessary to refer this application to the Medicines Assessment Advisors Group (MAAC). As such the information requested in these parts is refused under section 18(e) of the Act, as the information does not exist.

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: info@ombudsman.parliament.nz or by calling 0800 802 602.

Nāku noa, nā

Gill Hall
Group Manager
COVID-19 Science and Insights

Appendix 1: List of documents for release

#	Date	Document details	Decision on release
1	6 July 2021 – 17 August 2021	CV TAG Minutes	Excerpts provided in accordance with 16(e) of the Act.
2	4 August 2021	Memo: Priority groups for vaccination among 12- to 15-year-olds: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations on the use of the Pfizer vaccine	Released in full.
3	24 June 2021	Memo: Decision to use the Pfizer mRNA COVID-19 vaccine for children aged 12 -15 years: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations	

Document 1

Excerpt 1: CV TAG Minutes – 13 July 2021

4.0	**Myocarditis Recommendations**
	• Emerging evidence suggests one dose of the vaccine appears to be highly immunogenic, and provides greater protection in younger compared to older age groups, and therefore may provide sufficient protection in the interim, until further evidence emerges on second dose options.
	• CV TAG progressed to summarise an initial draft of the approach:
	  ○ The second dose of Pfizer vaccination could be deferred in individuals aged 29 years and under until further information is available about the risk, long-term outcomes of myocarditis and/or pericarditis, and protection offered by one dose for this age group.
	  ○ People 29 years of age and younger who require regular clinical review by a cardiologist are advised to discuss the risks and benefits of the first dose of COVID-19 vaccine for their specific situation with their healthcare team.
	  ○ People aged 30 years and over should still receive two doses of the vaccine, 21 days apart as the risk of myocarditis and/or pericarditis post vaccination is less than 1 in 400,000 and risks of severe disease and sequelae due to COVID-19, including myocarditis, are substantially higher in this age group compared to people aged 29 years and under.
	  ○ Anyone who develops confirmed myocarditis and/or pericarditis after the first dose should not receive a second dose of the Pfizer COVID-19 vaccine. CV TAG will consider alternative options for a second dose of COVID-19 vaccination in this group at a future date as evidence emerges from overseas safety monitoring.
	  ○ CV TAG will continue to monitor all relevant effectiveness and safety data closely and advise on the need and options for the second dose for individuals aged 29 years and under at a future date. Options for the second dose may include: 1) proceeding with the second dose of the Pfizer COVID-19 vaccine after a longer interval between doses; 2) not administering a second dose; 3) administering a second dose of an alternative COVID-19 vaccine.
	• A memo with these recommendations is being prepared and will be shared with CV TAG for feedback. Public-facing communications will be drafted for CVIP Communications. Options will need to remain agile as further evidence emerges.
	• Cardiac-related events associated with alternative vaccine schedules will be explored by the Science and Technical Advisory team, as will the use of other options.
	• Given that vaccinating the whānau together is a key approach for delivering the vaccine to Māori, further discussion will be needed on the equity implications of these recommendations.
	• The Director-General will need to be consulted about the options and the CVIP team will need to consider the implications for the programme.

Excerpt 2: CV TAG Minutes – 20 July 2021

5.0	**Myocarditis Recommendations Update** • Draft recommendations on the risk of myocarditis after Pfizer vaccination were discussed. ○ CV TAG noted that there is some evidence that young people aged 16 to 29 years have a strong immune response after one dose, however that two doses provide the best protection. A delayed schedule for the second dose was discussed. Whether

	this potentially reduces the risk of myocarditis, in addition to the severity of other adverse events, is unknown. ○ CV TAG recommended that for people aged 16 to 29 years the second dose be administered at least 8 weeks after the first.

Excerpt 3: CV TAG Minutes – 6 July 2021

6.0	• Myocarditis after Pfizer Vaccination • CV TAG discussed advice provided by the STA and a subgroup of CV TAG, on the current evidence on events of myocarditis/pericarditis post vaccination, and related questions. • Key points: • Previous studies of US military personnel, that evaluated the risk of myocarditis following the smallpox vaccine, indicated that myocarditis was a potential safety issue, with cases usually occurring within a few days of vaccination. • Events of myocarditis tend to be associated with the second dose of mRNA COVID-19 vaccines, although some cases occur after the first dose. The rate of myocarditis tends to be higher in males and younger age groups, particularly in males aged 16-30. • There is limited information, to date, on the long-term outcomes and severity of myocarditis following vaccination. Of the 29 cases in the Vaccine Safety Datalink (VSD) reported in the US, 24 (83%) were hospitalised with a median stay of 1 day (range 0-13 days), including two who were admitted to the ICU. All cases were discharged, and nearly all cases had resolution of symptoms at follow up. • Overall, emerging evidence suggests that myocarditis is a largely self-limiting and rare event following mRNA vaccination, with the rate for Pfizer in the US being approximately 0.8 per 100,000 in 12-39 year-olds within 21 days following the second dose. • CV TAG discussed possibility of alternative vaccination schedules that might mitigate the risk in younger age groups. However, any change in dosing schedule will require Medsafe approval. • CV TAG discussed potential recommendations, including advice for those with rheumatic heart disease, those with a previous history of myocarditis, or those who develop myocarditis following the first dose. • A subgroup of the CVTAG will meet 08 July to draft recommendations. The recommendations will be finalised by the end of week and discussed at the next CV TAG full meeting.

Excerpt 4: CV TAG Minutes – 20 July 2021

6.0	**Children Priority Groups** • Draft recommendations for potential priority groups among children were shared with the group, to inform the Decision to Use for 12- to 15-year-olds • Priority groups overseas have included children who are about to under long-term immunosuppression, immunocompromised, in long-term residential care, requiring

	transplants, or who have neurologic disabilities or gastrointestinal (multi-system medically vulnerable) conditions. Risk factors for COVID-19 such as obesity, respiratory disease, and ethnicity should also be taken into account. • CV TAG noted that the New Zealand's lack of community transmission was an important consideration for now, and vaccinating adults was the priority at this time. • STA will revise draft recommendations and share with CV TAG.

Excerpt 5: CV TAG Minutes – 27 July 2021

3.0	**Decision to Use Pfizer 12-15 year-olds** CV TAG reviewed the memo on the Decision to Use Pfizer for 12- to 15-year-olds (dated 24 June 2021). • CV TAG noted the potential for children to play a role in transmission in the community and the benefits of vaccination for children's personal protection. • CV TAG agreed that New Zealand's lack of community transmission was still an important consideration for now, and vaccinating adults was the priority at this time. • CV TAG agreed that exception should be made for priority groups of vulnerable 12 to 15 year-olds that are at higher risk from COVID-19 due to prior comorbidities, as outlined in the draft memo. CV TAG recommended vaccination progressing in these at-risk groups. • CV TAG recommended that the decision on vaccinating other 12–15 year-olds be deferred and reviewed at a future date, for example as the borders re-open and the immunisation of adults has progressed. A plan for vaccinating 12 to 15 year-olds should be in place in case of outbreak management. • CV TAG discussed the possibility of conducting trial research in New Zealand and Australia to compare the efficacy of single doses and two doses in 12 to 15 year-olds. Ongoing discussion of this option would be welcomed. • CV TAG noted that ATAGI's recommendations for 12 to 15 year-olds were under development, and that the Ministry would liaise closely with them, while noting the different portfolio of vaccines available in Australia may influence these decisions. • A memo on priority groups in 12-15 year olds will be provided to the Director-General and the COVID-19 Vaccine and Immunisation Programme (CVIP).

Excerpt 6: CV TAG Minutes – 3 August 2021

5.0	**Decision to Use Pfizer 12- to 15-year-olds and Children Priority Groups** • The challenges posed by the Delta variant and emerging data on differences in clinical severity among children were discussed with respect to vaccination in children. • Earlier advice had been that a broader decision on vaccinating 12- to 15-year-olds should be deferred. • Aotearoa New Zealand's lack of community transmission was noted as an important consideration in making this decision.

	• An exception should be made for priority groups of 12- to 15-year-olds that are at higher risk from COVID-19 due to prior comorbidities, as are outlined in the draft memo, which CV TAG supported. • Vaccinations as part of outbreak management, for example in schools, was also considered an exception. • Opportunities provided by mass vaccination events and vaccinating whānau together were noted as important considerations. • The Decision to Use for 12 to 15-year-olds and memo on priority groups will be provided to the Director-General and the COVID-19 Vaccine and Immunisation Programme (CVIP).
8.0	**MMR/Influenza Coadministration** • The Child and Community Health Group in the Ministry sought advice on the recommended intervals between receiving the COVID-19 vaccination and influenza or MMR vaccinations. The RfA on this topic was reviewed. • Currently a two-week gap between the COVID-19 vaccine and the influenza vaccine is recommended, and four-week gap with live vaccines such as MMR. • These intervals are a programmatic burden for the primary care sector and will become more so if vaccination in 12-15 year olds is progressed. • Based on first principles of vaccinology, it is not expected that there would be a problem with reducing timeframes, however it was noted that there are limited data from clinical trials or observational studies. • Preliminary results from trials and a summary of when data is expected should be included in the RfA by the Science and Technical Advisory team for CV TAG's review. STA will continue to monitor evidence as it emerges. • The Science and Technical Advisory team will bring together a working group to progress the discussion and draft recommendations, which will be brought back to CV TAG.

Excerpt 7: CV TAG Minutes – 17 August 2021

6.0	**Myocarditis after Pfizer Vaccination** An update on myocarditis cases was provided by the Chair: • The risk management communication relating to myocarditis was addressed with the announcement of the dosing interval extension. It was requested that references to increasing dosing intervals potentially providing some protection against myocarditis be removed from communications. This has been actioned. • An amendment to CV TAG's recommendations on myocarditis after Pfizer COVID-19 vaccination is needed to confirm that those "under clinical review by a cardiologist who should discuss the risk and benefits of vaccination" applies for 12- to 29-year-olds (and not 16- to 29-year-olds) once the extended age range has been approved and announced.
7.0	**Decision to Use Pfizer 12- to 15-year-olds** • CV TAG's recommendation that vaccination of 12- to 15-year-olds proceeds has been relayed to the Director-General and Vaccine Ministers.

	• Advice on promoting vaccination in whānau groups has been incorporated. • CV TAG requested the benefits of personal and family protection should be emphasised, rather than indirect benefits such as population protection. • The importance of vaccinating vulnerable groups among 12- to 15-year-olds was raised and discussed. It was noted that 12- to 15-year-olds considered Group 3 will be prioritised through another pathway and given codes to book.

Document 2

MINISTRY OF HEALTH
MANATŪ HAUORA

Memo

Priority groups for vaccination among 12- to 15-year-olds: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations on the use of the Pfizer vaccine

Date:	4 August 2021
To:	Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme
Cc:	Dr Ashley Bloomfield, Director-General of Health Maree Roberts, DDG, System Strategy and Policy Dr Caroline McElnay, Director of Public Health
From:	Dr Ian Town, Chief Science Advisor
For your:	Information

Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on priority groups for Pfizer mRNA COVID-19 vaccination among 12- to 15-year-olds.

Context

2. In June, CV TAG advice was sought for the use of the Pfizer mRNA COVID-19 vaccine for children aged 12 to 15 years, following the provisional approval for use in this age group by Medsafe.

3. At that time, CV TAG recommended that the rollout continue to focus on the existing population groups aged 16 years and over, and that any decision to use the COVID-19 vaccine in the 12- to 15-year-old age group should reflect that priority.

4. Generally, children have a lower risk of poor health outcomes from COVID-19 than adults. Internationally, a number of peak bodies, such as the US CDC, recommend that everyone 12 years and over should be vaccinated to help protect against COVID-19, in the context of widespread community transmission in the US.[1]

5. In Australia, the TGA has approved the Pfizer COVID-19 vaccine for ages 12 to 15 years.[2] On 2 August 2021, the Australian Technical Advisory Group on Immunisation (ATAGI) provided recommendations for vaccinating adolescents and children aged 12 to 15 years. ATAGI recommended that 12- to 15-year olds with specified medical conditions that increase their risk of severe COVID-19 be prioritised for vaccination (these conditions included asthma, diabetes, obesity, cardiac and circulatory congenital anomalies, neuro-developmental disorders, epilepsy, immunocompromised individuals, and trisomy). Aboriginal and Torres Strait Islanders aged 12 to 15 years were also prioritised, as well as all adolescents and

children aged 12 to 15 years in remote communities. ATAGI deferred a decision on whether to vaccinate all 12 to 15 year olds, and they expect to make that decision in the coming months.

6. In late 2020, the UK's Joint Committee on Vaccination and Immunisation (JCVI) advised that only children at very high risk of exposure and serious outcomes, such as those with severe neuro-disabilities in residential care, should be offered vaccination.[2] On 19 July 2021, the JCVI issued an update to their advice, stating that "*At the current time, children 12 to 15 years of age with severe neuro-disabilities, Down's syndrome, underlying conditions resulting in immunosuppression, and those with profound and multiple learning disabilities (PMLD)..., severe learning disabilities or who are on the learning disability register are considered at increased risk for serious COVID-19 disease and should be offered COVID-19 vaccination*".[4]

7. Furthermore, JVCI recommended that vaccination be offered to children and young people who have immunocompromised people in their household: "*JCVI advises that children and young people aged 12 years and over who are household contacts of persons (adults or children) who are immunosuppressed should be offered COVID-19 vaccination on the understanding that the main benefits from vaccination are related to the potential for indirect protection of their household contact who is immunosuppressed.*"[4] The recommendations from JVCI were made in the context of widespread community transmission.

8. Additionally, a North American study has found that 83% (40/48) of children in intensive care with COVID-19 had co-morbidities.[5] These were mostly "medically complex" (including long-term dependence on technological support, such as tracheostomy), immunosuppression/ malignancy, or obesity.

9. The Ministry's Policy team sought clinical and scientific advice from CV TAG on the use of the Pfizer COVID-19 vaccine for priority groups who are 12 to 15 years of age. This advice will be considered as part of the Decision to Use Framework and alongside policy considerations on the sequencing of the COVID-19 Immunisation Programme.

Recommendations

10. CV TAG met on 20 July, 27 July, and 3 August 2021 to discuss the use of the Pfizer COVID-19 vaccine in priority groups among 12- to 15-year-olds, within the COVID-19 Immunisation Programme.

11. **CV TAG noted that:**

    a. Aotearoa New Zealand's focus in the sequencing approach is on coverage of those most at risk of COVID-19 i.e., personal protection of individuals that may be more likely to be exposed to COVID-19 or experience severe health outcomes.

    b. The current recommendations are made in the context of the very low prevalence of COVID-19 in Aotearoa New Zealand. The recommendations may need to be reviewed in the event of new community transmission or outbreaks in Aotearoa New Zealand.

12. **CV TAG recommends that:**

    a. Children and young people aged 12 to 15 years should be vaccinated if they are at high risk of severe outcomes from COVID-19. Those at high risk include 12- to 15-year-olds with severe neuro-disabilities that require residential care, and those who

are about to undergo long-term immunosuppression, such as solid organ transplant candidates prior to transplant.

b. Children and young people aged 12 to 15 years who are household contacts of persons (adults or children) who are immunosuppressed should be offered vaccination noting that the main benefits from vaccination are related to the potential for indirect protection of their household contact who is immunosuppressed.

c. As part of outbreak management, vaccination should be offered to 12- to 15-year-olds in the affected area.

d. The COVID-19 vaccine should not be routinely administered to children and young people aged 12 to 15 years of age, at this time. Children and young people have a low risk of severe disease or death due to COVID-19 compared to adults, and, given the low prevalence of SARS-CoV-2 infection in Aotearoa New Zealand, there is currently a low risk of exposure.

e. CV TAG will make recommendations for use in all children in the 12 to 15 years age group at a later date, following a review of emerging information on several issues including:

   i. the safety and effectiveness of COVID-19 vaccines in adolescents as observed in overseas vaccination programmes;

   ii. the incidence, risk factors and outcomes of cases of myocarditis after receiving the Pfizer vaccine in this age group.

   iii. the updated advice from peak bodies internationally, including the updated advice from ATAGI on vaccinating children expected in the coming months.

f. Consideration should be given to equity and whānau-based approaches and ensuring that other childhood immunisation programmes are not compromised, e.g., measles and HPV vaccination.

13. CV TAG will continue to monitor all relevant information and will update their recommendations as further evidence and peak body recommendations become available.

Dr Ian Town

Chief Science Advisor and

Chair of the COVID-19 Vaccine Technical Advisory Group

References

1. COVID-19 Vaccines for Children and Teens. 23 July 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/recommendations/adolescents.html#:~:text=CDC%20recommends%20everyone%2012%20years,did%20prior%20to%20the%20pandemic.
2. TGA approves Pfizer COVID-19 vaccine for 12 to 15-year-olds. 23 July 2021. https://www.health.gov.au/ministers/the-hon-greg-hunt-mp/media/tga-approves-pfizer-covid-19-vaccine-for-12-to-15-year-olds
3. ATAGI statement regarding vaccination of adolescents aged 12–15 years: A statement from the Australian Technical Advisory Group on Immunisation (ATAGI) regarding vaccination of adolescents aged 12-15 years. 02 August 2021, https://www.health.gov.au/news/atagi-statement-regarding-vaccination-of-adolescents-aged-12-15-years
4. Joint Committee on Vaccination and Immunisation. Joint Committee on Vaccination and Immunisation: advice on priority groups for COVID-19 vaccination. 30 December 2020. https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/950113/jcvi-advice-on-priority-groups-for-covid-19-vaccination-30-dec-2020-revised.pdf
5. Public Health England. JCVI issues advice on COVID-19 vaccination of children and young people. 19 July 2021. https://www.gov.uk/government/publications/covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-jcvi-statement/jvci-statement-on-covid-19-vaccination-of-children-and-young-people-aged-12-to-17-years-15-july-2021
6. Shekerdemian LS, Mahmood NR, Wolfe KK, et al. Characteristics and Outcomes of Children With Coronavirus Disease 2019 (COVID-19) Infection Admitted to US and Canadian Pediatric Intensive Care Units. JAMA Pediatr 2020; 174(9): 868-73.

Document 3

Memo

Decision to use the Pfizer mRNA COVID-19 vaccine for children aged 12 -15 years: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	24 June 2021
To:	Joanne Gibbs, Director of National Operations, COVID Vaccine Immunisation Programme
Cc:	Dr Ashley Bloomfield, Director-General of Health Allison Bennett, Manager, System Enablers, System Strategy and Policy Dr Caroline McElnay, Director of Public Health
From:	Dr Ian Town, Chief Science Advisor
For your:	Information

Purpose of report

1. To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) recommendations on the decision to use the Pfizer mRNA COVID-19 vaccine for children aged 12-15 years.

Context

2. In February 2021, CV TAG advice was sought for use of the Pfizer COVID-19 vaccine for people who were 16 years and over following Medsafe provisional approval.
3. Cabinet agreed that the COVID-19 Immunisation Programme proceed with the roll out of the Pfizer COVID-19 vaccine. It was noted that there were no specific exclusions for the use of the vaccine that would materially impact on the Sequencing Framework or the Immunisation Programme delivery.
4. It was also noted at the time that clinical trials had not yet concluded for those under 16 years and that once further paediatric trials are reported that Medsafe would be able to consider broadening the approval conditions for the Pfizer vaccine.
5. Medsafe has recently granted provisional approval conditions for the Pfizer vaccine to include people who are 12 years of age and over.
6. The Ministry's Policy team sought clinical and scientific advice from CV TAG on the use of the Pfizer COVID-19 vaccine for people who are 12-15 years of age. This advice will be considered as part of the Decision to Use Framework and alongside policy considerations on the sequencing of the COVID-19 Immunisation Programme.

Recommendations

7. CV TAG met on 22 June 2021 and discussed the use of the Pfizer COVID-19 vaccine in children aged 12-15 years.

8. CV TAG noted:

    - our focus in the sequencing approach is on coverage of those most at risk of COVID-19 ie, personal protection of individuals that may be more likely to be exposed to COVID-19 and/or experience severe health outcomes
    - our current context relating to the very low prevalence of COVID-19 in New Zealand
    - generally, children have a lower risk of poor health outcomes from COVID-19 infection
    - there is a relatively limited amount of data from the trials as well as limited experience internationally, which makes it difficult to provide certainty about the risks and benefits of vaccinating this age group
    - there is a potential safety signal for myocarditis in people under 30 years who receive mRNA vaccines (e.g., Pfizer/BioNtech and Moderna), which requires ongoing consideration
    - overall, there is not an urgent need to progress with vaccination of this group, but consideration should be given to equity and whānau-based approaches and ensuring that other childhood immunisation programmes are not compromised, e.g., measles and HPV vaccination.

9. CV TAG recommended that the rollout continue to focus on the existing population groups aged 16 years and over that are at risk of COVID-19 and that any decision to use the COVID-19 vaccine in the 12-15 age group should reflect this current priority.

Dr Ian Town

Chief Science Advisor and

Chair of the COVID-19 Vaccine Technical Advisory Group