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M.R.M

By email: fyi-request-17594-08c9f2a3@requests.fyi.org.nz
Ref: H202116355

Tēnā koe M.R.M.

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 office of the Minister for COVID-19, Hon Minister Hipkins to the Ministry of Health (the Ministry) on 17 November 2021.

Each part of your request is responded to below:

> *Please provide me with the following information:*
> *1. The date on which the abovementioned agreement* [for the provision of the AstraZeneca COVID-19 vaccination] *was signed.*
> *1.a. The number of doses ordered under the abovementioned agreement.*
> *1.b. The anticipated, targeted or agreed delivery date of the abovementioned doses. (If more than one date applies please provide all of the dates).*
>
> *2. The date on which the Pfizer / BioNTech agreement was signed.*
> *2.a. The number of doses ordered under the abovementioned agreement.*
> *2.b. The anticipated, targeted or agreed delivery date of the abovementioned doses. (If more than one date applies please provide all of the dates).*
>
> *3. The date on which the Janssen Pharmaceutical agreement was signed.*
> *3.a. The number of doses ordered under the abovementioned agreement.*
> *3.b. The anticipated, targeted or agreed delivery date of the abovementioned doses. (If more than one date applies please provide all of the dates).*
>
> *4. The date on which the Novavax agreement was signed.*
> *4.a. The number of doses ordered under the abovementioned agreement.*
> *4.b. The anticipated, targeted or agreed delivery date of the abovementioned doses. (If more than one date applies please provide all of the dates).*

The information you have requested is provided in the table overleaf.

Vaccine candidate	Date of signing	Volume	Anticipated, target, or agreed date of shipment
AstraZeneca	3 November 2021	100,000 doses - redirection from original advance purchase agreement (APA) volume	18 November 2021 Information available at: covid19.govt.nz/news-and-data/latest-news/astrazeneca-arrives-in-new-zealand-second-covid-19-vaccine-available-this-month/
Pfizer	22 December 2020	Original APA for 1.5 million doses	Weekly from 15 February 2021. Information available at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-data-and-statistics/covid-19-vaccine-data
Janssen	22 December 2020	Original APA for 2 million doses with an option to purchase an additional 3 million	Withheld under section 9(2)(b)(ii) of the Act where the making available of the information would be likely unreasonably to prejudice the commercial position of the person who supplied or who is the subject of the information
Novavax	15 December 2020	Original APA for 10.72 million doses	

5. A full disclosure explanation as to why the New Zealand public were not given the choice of at least two vaccines from the start of the vaccination programme on 20 February 2021.

In March 2021, the New Zealand Government guaranteed that everyone eligible in New Zealand would have access to the COVID-19 Pfizer vaccine. The decision to make the Pfizer vaccine the primary vaccine of the vaccine programme was based on timely access to a safe and effective vaccine. The Pfizer vaccine was originally the only vaccine with provisional consent from Medsafe, which had been shown to be 95% effective at preventing symptomatic COVID-19 infection, and doses were available for use in New Zealand. The initial utilisation of one vaccine in the programme reduced the complexity of implementing multiple vaccine protocols.

6. A full disclosure explanation as to why the AstraZeneca vaccine is only being made available almost 9 months after the Pfizer vaccine was first made available (on 20 February 2021), and, at a time when the majority of the New Zealand public have already had two Pfizer vaccinations.

As noted above, the Pfizer Comirnaty COVID-19 vaccine was the only vaccine option made available for a variety of reasons.

Through discussion with AstraZeneca and the Australian Government, the Government engaged in an agreement to divert 100,000 doses of the AstraZeneca vaccine, from Australian manufacturing sites to New Zealand in November 2021. This process was undertaken to ensure that an alternative COVID-19 vaccine was available to increase vaccine uptake particularly for those people unable or unwilling to take the Pfizer vaccine,

especially those required to be vaccinated by the COVID-19 Public Health Response Order 2021 or their employer.

> *7. A full disclosure explanation as to why your office/department only made it known to the New Zealand public in recent days that it had signed an agreement for 7.6 million doses of the Astra Zeneca vaccine, and, - more importantly - that delivery of same would happen by around the end of November 2021. In other words, why was this crucial information withheld from the New Zealand public given the likelyhood that a large number of the New Zealand public would probably have chosen the Astra Zeneca - a viral vector (non-MRNA) - vaccine rather than the Pfizer - a MRNA - vaccine.*

On 17 December 2020, the New Zealand Government announced the agreement to buy 7.6 million doses of the AstraZeneca vaccine. Information about the agreement is available at: www.beehive.govt.nz/release/two-new-vaccines-secured-enough-every-new-zealander.

On 22 July 2021, Medsafe granted provisional approval to the AstraZeneca vaccine, enabling domestic use and international donations of the vaccine. This was followed by a press release on 29 July 2021 notifying the public of the vaccine's provisional approval and the Government's intention to use AstraZeneca vaccines to support the Pacific region's vaccination efforts, while continuing with a Pfizer-based domestic vaccination programme.

Information about the AstraZeneca vaccine provisional approval is available at: www.beehive.govt.nz/release/third-covid-19-vaccine-receives-provisional-approval. In November 2021, New Zealand entered an agreement with the Australian Government and AstraZeneca to obtain 100,000 doses of the AstraZeneca vaccine from Australian manufacturing sites.

> *8. Given your comment about the "very small" number of people who will be able to have the Astra Zeneca vaccine, a full disclosure explanation as to why an undisclosed limit has been placed on this vaccine, how it was calculated what number of doses of the Astra Zeneca vaccines would be needed by the New Zealand public, and why New Zealand agreed to purchase 7.6 million doses of the Astra Zeneca vaccine when a) its arrival in New Zealand comes too late for the very large number of employees who have been mandated to be vaccinated by today's date or lose their jobs, and b) large numbers of New Zealanders have complained over the past months that they were not given a choice of vaccine with the Pfizer vaccine still being the only one currently available.*

This process was undertaken to ensure that an alternative COVID-19 vaccine was available for those people unable or unwilling to take the Pfizer vaccine, particularly for those required to be vaccinated by the COVID-19 Public Health Response Order 2021 or their employer. This volume (100,000 doses or 50,000 courses) was derived by estimating the small number of people unable to receive or hesitant of receiving the Pfizer vaccine. Additional considerations included limiting vaccine wastage, recommendations from COVID-19 Vaccine Technical Advisory Group on use of the AstraZeneca vaccine, and the option to obtain further doses if necessary.

> *Lastly, please provide me with a copy of the criteria document which clearly sets out who does and who does not qualify for having the Astra Zeneca vaccine given your "over 18s who are unable to have the Pfizer vaccine for medical reasons, and for people hesitant to receive the Pfizer vaccine" comment.*

Please see the document *Decision to use the AstraZeneca COVID-19 vaccine: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations* attached for further information about the decision to use AstraZeneca COVID-19 vaccines in New Zealand.

The eligibility and exclusion criteria for the AstraZeneca vaccine can be found at: www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-vaccines/covid-19-vaccine-health-advice/covid-19-getting-other-vaccines/covid-19-astrazeneca-vaccines.

I trust this information fulfils your request. 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.

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

Nāku noa, nā

Maree Roberts
Deputy Director-General
System Strategy & Policy

Memo

Decision to use the AstraZeneca COVID-19 vaccine: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	27th October 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 AstraZeneca COVID-19 vaccine ('the AstraZeneca vaccine').

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. Cabinet agreed that the COVID-19 Vaccine Immunisation Programme proceed with the rollout of the Pfizer vaccine. It was noted that further advice would be provided to Cabinet on each vaccine candidate as they became available for use (following Medsafe approval), without knowing if a future vaccine was going to be more suitable or effective. In order to make decisions given the uncertainty, a Decision to Use framework was developed.

3. In July 2021, CV TAG advice was sought on the use of the Janssen COVID-19 vaccine for people aged 16 years and over, following Medsafe provisional approval. CV TAG advised that there was no current indication for wide use of the Janssen vaccine, however that it could be considered at an individual level where the Pfizer vaccine was not suitable e.g., anaphylaxis or other rare side effects following the first dose of the Pfizer vaccine. Cabinet considered the recommendations for the Decision to Use the Janssen vaccine and agreed to proceed with taking receipt of up to 500,000 doses in October 2021 for those individuals unable to receive the Pfizer vaccine (e.g., anaphylaxis), or for people who are hesitant to receive a messenger RNA (mRNA) vaccine.

4. At the time Cabinet made this decision, it was expected that Janssen's vaccine would be available in New Zealand in Q4 2021. However, as a result of subsequent regulatory issues relating to the manufacture of Janssen's vaccine, it is unlikely that Janssen will be able to provide supply any earlier than January 2022. Given the uncertainty around accessing

Janssen's vaccine in 2021, the Ministry's Policy team are looking to secure supply of the AstraZeneca vaccine in the coming weeks.

5. The Ministry's Policy team sought clinical and scientific advice from CV TAG on the use of the AstraZeneca vaccine in New Zealand.

6. The AstraZeneca vaccine was granted provisional approval by Medsafe for use in people aged 18 and over in New Zealand on 22 July 2021, under section 23 of the Medicines Act, with conditions.[1]

7. It is a two-dose non-replicating viral vector vaccine, and the second dose is administered between 4 and 12 weeks after the first dose. It can be stored at 2-8°C for up to 6 months. Multiple doses may be pre-drawn from one vial and used within one hour if stored at room temperature, or within six hours if stored at 2-8°C.[2]

8. The overall safety and efficacy of the AstraZeneca vaccine is based on analysis of pooled data from four phase III clinical trials (COV001, COV002, COV003, and COV005) conducted in the United Kingdom (UK), Brazil, and South Africa. At the time of analysis, 24,244 participants aged 18 and over had been randomised and received either the AstraZeneca vaccine or control. Additional safety of the AstraZeneca vaccine was established in a randomised phase III clinical trial conducted in the United States, Peru, and Chile.[3, 4]

9. The AstraZeneca vaccine provides efficacy against COVID-19 infection and severe disease. Vaccine efficacy against symptomatic, lab-confirmed, COVID-19 at least 14 days after two standard doses, with 4-to-12-week intervals, was 63.1% (95%CI: 51.8-71.1) in pooled data from the trials conducted in the UK, Brazil and South Africa.[3] In the US, Chile, and Peru trial, efficacy was 74% (95%CI: 65.3-80.5) from 15 days after the second dose when given four weeks apart.[4] Efficacy against severe disease or hospitalisation was found to be 100% (95% CI 72.2-100%) from >21 days after the second dose across clinical trials.[3, 4]

10. Intervals between doses varied in clinical trials, and post hoc analysis indicated that longer intervals were associated with a stronger immune response. When the dose interval was stratified in the initial phase III trial, an interval of <6 weeks was associated with 55.1% (95%CI 33.0-69·9%) efficacy, at 6-8 weeks it was 59·9% (95%CI 32.0–6.4%), at 8-11 weeks it was 63.7% (95%CI 28.0-81.7%) and ≥12 weeks it was 81.3% (95%CI 60.3 – 91.2%).[5]

11. Estimates for effectiveness against viral infection ranged from 73% to 94.9% pre-Delta,[6-9] and against severe disease were 72.8% (95%CI: 71.8-73.8).[10] Real world effectiveness has seen a modest decline, however it is unclear if this is due to Delta or waning efficacy of the vaccine. Results from a UK study demonstrated high vaccine effectiveness against hospitalisation, however it declined from 93.9% (95% CI: 91.3%-95.7%) at 1 week after the second dose to 77% (95% CI: 70.3%-82.3%) at 20+ weeks. Effectiveness against symptomatic COVID-19 also declined from 62.7% (95% CI: 61.7%-63.8%) at 1 week after the second dose to 47.3% (95% CI: 45%-49.6%) at 20+ weeks.[11] Effectiveness against death was 94.1% (95%CI: 91.8-95.8) at 2-9 weeks after the second dose and then fell to 78.7% (95%CI: 52.7-90.4) by 20+ weeks.[11]

12. Data about effects on transmission remain limited. Unvaccinated members of a household, in which the primary infection is someone vaccinated with one dose of AstraZeneca, were (for respectively AstraZeneca, and AstraZeneca and Pfizer together) around 40-50%,[12] and 30%,[13] less likely to become a secondary infection compared to those in unvaccinated healthcare worker households.

13. Continued safety monitoring is essential to understand the long-term safety profile of this platform.

    a. Severe occurrences of various systemic reactions after the first dose were reported in <10% 18-55 year olds in the phase I/II trial, which were reduced with the use of prophylactic paracetamol.[14] The most frequent solicited adverse events (reported in more than 1 in 10 people) were injection-site tenderness and pain, feeling feverish (pyrexia), chills, myalgia, headache, malaise, arthralgia, and nausea.[14, 15] Systemic adverse events of all severities were less common in those over 55 years compared to younger adults, and also less common after a second dose.[16] Overall, reactogenicity rates appear higher among ≤ 50 than > 50 year-olds, women and those with prior symptomatic/confirmed COVID-19.[17]

14. *Thrombosis with thrombocytopaenia syndrome (TTS):* A very rare and serious syndrome called thrombosis with thrombocytopaenia syndrome (TTS) has been observed following vaccination with the AstraZeneca vaccine during post-marketing use. This includes cases presenting as venous thrombosis, including unusual sites such as cerebral venous sinus thrombosis (CVST), splanchnic vein thrombosis, as well as arterial thrombosis, concomitant with thrombocytopenia.[18]

    a. The European Medicines Agency (EMA) concluded on 8 April 2021 that there was a strong relationship between TTS coagulation disorders and administration of the vaccine, such as disseminated intravascular coagulation, CVST, as well as arterial thromboembolic and haemorrhagic stroke. According to the EMA, a total of 1,503 cases had been reported worldwide as of 31 July 2021, while around 592 million doses of the AstraZeneca vaccine had been administered by 25 July 2021. The majority of the events occurred within the first 21 days following vaccination but have also been reported after this period.[19-21]
    b. Whilst specific risk factors for thromboembolism in combination with thrombocytopenia have not been identified, cases have occurred in patients with a previous history of thrombosis, as well as in patients with autoimmune disorders, including immune thrombocytopenia.[18]
    c. Up to 6 October 2021, there were 424 cases of TTS reported to the UK's MHRA following vaccination with AstraZeneca, of which 46 were following the second dose. Of the 424 reports, 213 occurred in women, and 207 occurred in men aged from 18 to 93 years. The overall case fatality rate was 17% with 72 deaths, six of which occurred after the second dose. This equates to 15.2 cases reported per million first doses.[22]
    d. In Australia, the risk of developing TTS after a first dose of AstraZeneca was estimated to be 20 in a million.[23] As of 17 October, there have been 156 cases of TTS assessed as related to the AstraZeneca vaccine in Australia from approximately 12.6 million vaccine doses. These cases most often occurred about 2-3 weeks after vaccination. The risk of TTS after a second dose appears to be much lower than after the first dose. The risk of dying from TTS after vaccination is reported to be approximately 1 in a million (for people receiving a first dose), and somewhat less than this when both doses are taken into consideration.[24]
    e. The incidence rate is higher in the younger adult age groups following the first dose compared to older age groups. According to data from the UK's MHRA, the incidence

rate is 20.9 per million doses in those aged 18-49 years, compared to 10.9 per million doses in those aged 50 years and over.[22] According to data from Australia's COVID-19 vaccine weekly safety report up to 21 October 2021, the reporting rate of TTS remains higher in people aged under 60 years (2.5 per 100,000 doses) compared to those aged 60 and over (1.8 per 100,000 doses). Women in younger age groups seem to be slightly more likely to develop clots in unusual locations, such as the brain or abdomen, which have more serious outcomes. Eight people have died as a result of TTS, and of those six were women.[24]

15. *Guillian-Barré syndrome (GBS).* GBS has been reported very rarely following vaccination with the AstraZeneca vaccine.[18] At the EMA Pharmacovigilance Risk Assessment Committee (PRAC) meeting from 05-08 July 2021, it was recommended that a warning for GBS following vaccination be added to the data sheet. They did not ascribe causality but concluded that it is possible that GBS is a side effect of the vaccine.[25] On 08 September, the EMA added GBS following vaccination as a very rare side effect to the AstraZeneca product information sheet.[26]
16. *Capillary leak syndrome (CLS).* Very rare cases of CLS have been reported in the first days after vaccination with the AstraZeneca vaccine. A history of CLS was apparent in some of these cases. Fatal outcome has been reported.[18] Both the UK's MHRA and the EMA's PRAC recommend that people with a history of CLS should not receive the vaccine.[27, 28] On 10 June 2021, PRAC recommended that CLS be added as an adverse reaction for the AstraZeneca vaccine.
17. Several countries have restricted the use of the AstraZeneca vaccine in different age groups, including Australia, Canada, Germany and the UK.[29-32]
    a. In Australia, the Australian Technical Advisory Group on Immunisation (ATAGI) has provided guidance about the risk-benefit for the AstraZeneca vaccine by age group. In a large outbreak, ATAGI advises that the benefits of the AstraZeneca vaccine are greater than the risk of rare side effects for all age groups. Where background risk of COVID-19 exposure and disease is low, AstraZeneca vaccine is recommended only for people aged 60 and over. However, anyone aged 18 to 59 years can choose to receive the AstraZeneca vaccine either following discussion with a qualified health professional, or if they provide verbal or written consent. Most people have their second dose 12 weeks after their first, but ATAGI recommends 4 to 8 weeks between the first and second doses in an outbreak so maximal protection against COVID-19 can be achieved earlier.[23]
    b. In Canada, the National Advisory Committee on Immunisation recommends the AstraZeneca vaccine for individuals 30 years of age and older who do not wish to wait for an mRNA vaccine, expanded from its previous guidance of a higher age limit of 55 years because of concerns over TTS.[31]
    c. In the UK, MHRA recommend adults aged 18-39 years with no underlying health conditions are offered an alternative to the Oxford-AstraZeneca vaccine, if this does not cause delays in having the vaccine.
18. This advice should be considered as part of the Decision to Use Framework and alongside policy considerations on the sequencing of the COVID-19 Vaccine and Immunisation Programme.

Recommendations

19. CV TAG met on 19 October to discuss use of the AstraZeneca COVID-19 vaccine, noting the information provided in the Pfizer vaccine Data Sheet.

20. **CV TAG noted that**:

a. The contraindications for the AstraZeneca vaccine are:[18]

i. Hypersensitivity to the active substance or to any of the excipients.
ii. Patients who have experienced major venous and/or arterial thrombosis with thrombocytopenia following vaccination with any COVID-19 vaccine.
iii. Individuals who have previously experienced episodes of capillary leak syndrome.

b. COVID-19 disease is associated with many complications including the development of blood clots. Administration of the AstraZeneca vaccine is rarely associated with thrombosis and thrombosis with thrombocytopaenia syndrome (TTS). TTS has a higher incidence among younger populations which is important to be aware of, however the risk is much less common than thrombotic complications from the COVID-19 disease itself.

c. In general, the Pfizer vaccine offers a higher level of protection than the AstraZeneca vaccine. The efficacy of the AstraZeneca vaccine against symptomatic, laboratory confirmed COVID-19 at least 14 days after two standard doses, with 4-to-12-week intervals, was 63.1% (95%CI: 51.8-71.1)[3], compared to 95% (95%CI: 90.3-97.6) for the Pfizer vaccine.[33] However the AstraZeneca vaccine still provides high protection and efficacy against infection, disease, and death.

d. Data are still emerging on the safety and efficacy of heterologous ("mixed dose") vaccine schedules from approved vaccines in New Zealand. Initial results show that mixed schedules of the Pfizer vaccine with the AstraZeneca vaccine (for example, one dose of AstraZeneca followed some weeks later by one dose of Pfizer) is associated with an acceptable reactogenicity profile and generates levels of anti-spike neutralising antibody equivalent or greater than those associated with high levels of protection in primary efficacy trials.[34-36] In the UK COM-COV study, participants were randomised to a first dose of Pfizer with a second dose of AstraZeneca 4-weeks later. Antibody responses were inferior to two doses of Pfizer/BioNTech (homologous).[36] The relevance of this to clinical effectiveness is unknown, though the vaccine schedule was still considered to provide protection.

e. Data on safety and efficacy of the AstraZeneca vaccine in people aged less than 18 years and old and in pregnant women, or women who became pregnant after receiving the vaccine, are limited. Medsafe consider available data insufficient to assess risk-benefit in people aged less than 18 years old or pregnant women.[18]

f. The AstraZeneca vaccine is included as part of the ComFluCOV study looking at the safety and immunogenicity of concomitant administration of AstraZeneca or Pfizer COVID-19 vaccines with three different seasonal influenza vaccines in adults. Most reactions were mild to moderate, with local and unsolicited systemic reactions similar between randomised groups. No significant difference was observed regardless of whether the shots were given on the same day or 3-4 weeks apart.[37]

21. **CV TAG recommends that:**

a. The COVID-19 Vaccine Immunisation Programme use the AstraZeneca vaccine as a second-line vaccine, with Pfizer remaining the first-line and preferred vaccine.

b. Use of the AstraZeneca vaccine be restricted to people who have a contraindication to the Pfizer vaccine, or people who would prefer to get the AstraZeneca vaccine and are currently under a Vaccination Order, or who are unvaccinated or incompletely vaccinated and hesitant about getting the Pfizer vaccine.

c. Within the groups outlined in 21)b, the AstraZeneca vaccine be made available to the following eligible groups:

i. People aged 60 years and over without contraindications.

ii. People aged 18 to 59 without contraindications and who prefer to receive the AstraZeneca vaccine after discussion with a qualified health professional.

d. There is currently insufficient data on the AstraZeneca COVID-19 vaccine to recommended it during pregnancy. Use in pregnancy should be based on an assessment of benefits and risks by the consumer and their healthcare professional.

e. With regard to timing:

i. two doses of the AstraZeneca vaccine, given 4 to 12 weeks apart, are necessary to be considered fully vaccinated.

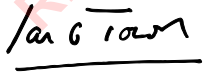
ii. a shorter interval of more than 4 to less than 8 weeks between the first and second doses is recommended in an outbreak to provide earlier protection.

iii. administration of the AstraZeneca vaccine as a second dose should occur at least 28 days after the most recent dose of another COVID-19 vaccine.

iv. there be no upper limit on time since the last dose.

v. the AstraZeneca vaccine may be administered before, after, or at the same time as the influenza, MMR, HPV, diphtheria/tetanus/pertussis combination vaccine (Boostrix), and other vaccines. The only exception to this advice is for the live-attenuated shingles vaccine (Zostavax) where a 7-day interval, before or after administering the AstraZeneca vaccine is advised.

22. CV TAG will continue to monitor the evidence and will update their recommendations as data become available.



Dr Ian Town

Chief Science Advisor and

Chair of the COVID-19 Vaccine Technical Advisory Group

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