Memo

Decision to use the Novavax COVID-19 vaccine (Nuvaxovid) in those aged 12 to 17 years: COVID-19 Vaccine Technical Advisory Group (CV TAG) recommendations

Date:	25 August 2022
To:	Dr Diana Sarfati, Director-General of Health
Copy to:	Dr Andrew Old, Deputy Director-General, Public Health Agency Astrid Koornneef, Director, National Immunisation Programme (NIP) Allison Bennett, Manager, System Enablers, System Strategy and Policy
From:	Dr Dan Bernal, Acting Chief Science Advisor
For your:	Consideration

Purpose of report

1 To summarise the COVID-19 Vaccine Technical Advisory Group's (CV TAG) advice about the use of the Novavax COVID-19 vaccine (Nuvaxovid) in those aged 12-17 years.

Background and context

2 The Novavax COVID-19 vaccine (Nuvaxovid) was approved by Medsafe on 4 February 2022 for use in New Zealand as a primary course for those 18 years of age and older.[1] It has since been authorised as a homologous or heterologous booster dose (i.e. after Nuvaxovid primary course, or after a primary course of another brand of COVID-19 vaccine) in the same age group.

3 Nuvaxovid has been authorised for 12–17 year-olds in a number of jurisdictions including the European Union and Australia.[2, 3] The vaccine is given to this age group with the same schedule (two primary doses, three weeks apart) and the same formulation as adults.

4 On 18 August 2022 Medsafe approved an application from Novavax for the use of Nuvaxovid as a primary course in those aged between 12 and 17 years of age (inclusive). The Pfizer COVID-19 vaccine (Comirnaty, adult formulation) has been authorised by Medsafe for use as a primary course in those aged 12 years and older.[4] Those aged 16 years and older are also eligible for a booster vaccination with Comirnaty in New Zealand if it is 6 months or more since they completed their primary course. Those aged 12 -15 years (unless severely immunocompromised), are not yet eligible for a booster dose (of any COVID-19 vaccine) in New Zealand.

5 Currently, those 12-17 years of age (the age group under consideration in this memo) can receive Pfizer COVID-19 vaccine (Comirnaty, adult formulation), which has been authorised by

Medsafe for use as a primary course in those aged 12 years and older.[4] Those aged 16 years or older are also eligible for a booster vaccination with Comirnaty in New Zealand if it is 6 months or more since they completed their primary course. Those aged 12 -15 years are not yet eligible for a booster dose (of any COVID-19 vaccine) in New Zealand.

6 The Ministry of Health has asked CV TAG to provide advice on whether or not Nuvaxovid should be made available as a primary COVID-19 vaccination course to those aged 12-17 years in New Zealand.

Data about Nuvaxovid COVID-19 vaccine in 12 – 17 year olds

7 There are very limited data available about the use of Nuvaxovid in those aged 12-17 years. Data from a study including over 2,200 children aged 12-17 years is being considered by regulatory authorities,[5] but the details of these data have not yet been released by either Nuvaxovid or regulatory authorities. However, a summary of the trial data has been released by the European Medicines Agency (EMA) in a press release:[2]

7.1 "This trial showed that the immune response to Nuvaxovid in adolescents, which was measured as the level of antibodies against SARS-CoV-2, was comparable to the response in young adults aged 18 to 25 years (who were part of the main study used to assess effectiveness of the vaccine in adults). The trial was carried out when the SARS-CoV-2 Delta variant was dominant and showed that the vaccine was almost 80% effective at preventing COVID-19; six out of the 1,205 adolescents who received Nuvaxovid developed COVID-19 compared to 14 out of 594 who received placebo. The CHMP considered that these results are in line with those seen in adults".

7.2 "The most common side effects in adolescents are mostly similar to those in people aged 18 and above. They include tenderness, pain, redness and swelling at the injection site, headache, muscle and joint pain, tiredness, generally feeling unwell, feeling sick or vomiting and fever. Fever is seen more frequently in adolescents than in adults. These effects are usually mild or moderate and improve within a few days of vaccination."

8 Data about the effects of Nuvaxovid are also limited in those aged 18 and older, because Nuvaxovid has not yet been administered to large numbers of people compared to some other COVID-19 vaccines. There are currently no data about vaccine effectiveness against Omicron and limited data about the safety of Nuvaxovid in those aged over 18 years.

9 Small amounts of data about myocarditis and pericarditis are available from jurisdictions using Nuvaxovid (principally Australia and the European Union (EU)). From Australian and EU data, there is currently no strong evidence to indicate that the risk of myocarditis/pericarditis is lower after Nuvaxovid than after Comirnaty:

9.1 In Australia, data to June 26th 2022 indicate 160,000 doses of Nuvaxovid had been given, with 6 cases of myocarditis (38 cases per million doses) and 29 cases pericarditis (181 cases per million doses) reported.[6] Although these frequencies are higher than after Comirnaty vaccine in Australia (25 per million doses for myocarditis, 71 per million doses for pericarditis) it should be noted that this is based on a relatively small number of doses and cases.[6] Additionally, there are potential biases (for example, Nuvaxovid may have been administered to younger age groups which are more likely to experience myocarditis, but doses by age group have not yet been reported) limiting comparisons between observed frequency of events between vaccines.

9.2 Data from the EU to 23rd July 2022 indicate 250,091 doses of Nuvaxovid had been given, with 6 cases of myocarditis (24 cases per million doses) and 6 cases pericarditis (24 cases per million doses) reported.[6] These frequencies are similar to or slightly lower than after Comirnaty in the EU (34 per million doses for myocarditis, 23 per million doses for pericarditis).[6]

9.3 Data on severity of myocarditis and pericarditis from these jurisdictions haven't yet been publicly reported.

Recommendations

10 CV TAG met on 16th August 2022 to discuss the decision to use Nuvaxovid (Novavax COVID-19 vaccine) in those aged 12-17 years old.

11 CV TAG noted that:

11.1 Safety, immunological and efficacy data about the use of Nuvaxovid in 12-17 year olds are limited.

11.2 The recommendations provided in this document relate to a primary course of Nuvaxovid vaccination in 12-17 year olds.

11.3 There is limited data on Nuvaxovid as a booster among 12-17 year olds. Consideration of Nuvaxovid as a booster for 12-17 year olds will require off-label administration.

12 CV TAG recommended that:

12.1 Comirnaty (Pfizer) remains the preferred vaccine in those aged 12 years and above in New Zealand. However, Nuvaxovid should be made available for use as an alternative option as a primary course in those aged 12-17 years of age following the schedule authorised by Medsafe (2 doses, 3 weeks apart).

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

Dr Dan Bernal

Acting Chief Science Advisor and

Acting Chair of the COVID-19 Vaccine Technical Advisory Group

References

1. Medsafe - New Zealand Medicines and Medical Devices Safety Authority. *New Zealand Data Sheet - Nuvaxovid. Version 4*. 22 June 2022; Available from: https://www.medsafe.govt.nz/profs/Datasheet/n/Nuvaxovidinj.pdf.
2. European Medicines Agency (EMA). *EMA recommends authorisation of Nuvaxovid for adolescents aged 12 to 17*. 23 June 2022; Available from: https://www.ema.europa.eu/en/news/ema-recommends-authorisation-nuvaxovid-adolescents-aged-12-17.
3. Therapeutic Goods Administration. *TGA provisionally approves the Biocelect Pty Ltd (Novavax) COVID-19 vaccine, NUVAXOVID, for use in individuals aged 12-17 years*. 25 July 2022; Available from: https://www.tga.gov.au/media-release/tga-provisionally-approves-biocelect-pty-ltd-novavax-covid-19-vaccine-nuvaxovid-use-individuals-aged-12-17-years.
4. Medsafe - New Zealand Medicines and Medical Devices Safety Authority. *New Zealand Data Sheet - Cominarty. Version pfdcovii10622*. 2 June 2022; Available from: https://www.medsafe.govt.nz/profs/Datasheet/c/comirnatyinj.pdf.
5. Novavax. *A Study to Evaluate the Efficacy, Immune Response, and Safety of a COVID-19 Vaccine in Adults ≥ 18 Years With a Pediatric Expansion in Adolescents (12 to<18 Years) at Risk for SARS-CoV-2*. 5 Aug 2022; Available from: https://clinicaltrials.gov/ct2/show/NCT04611802.
6. Airfinity. *Airfinity Science Tracker*. 2022; Available from: https://www.airfinity.com/.