Memo

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

Date:	5 February 2021
To:	Dr Ashley Bloomfield, Director-General of Health
Cc:	Dr Ian Town, Chief Science Advisor
From:	Dr Caroline McElnay, Director of Public Health
For your:	Information

Purpose of report

1. To outline the COVID-19 Vaccine Technical Advisory Group's recommendations on for whom the Pfizer mRNA COVID-19 vaccine is appropriate.

Context

2. Following Medsafe's provisional approval of the Pfizer mRNA COVID-19 vaccine (Comirnaty, BNT162b2) for people 16 years and over on 3 February 2021, the COVID-19 Vaccine Technical Advisory Group (CV TAG) met on 4 February 2021 to provide the scientific and technical assessment of the Pfizer mRNA COVID-19 vaccine, including advice on who is to receive the vaccine.
3. The CV TAG has completed a scientific and technical assessment of the Pfizer mRNA COVID-19 vaccine, in order to provide these recommendations.

Recommendations

4. The CV TAG recommends that:
    a. the Pfizer mRNA COVID-19 vaccine is suitable for use in New Zealand for all people 16 years of age and over, including for people over 65 years;[1]
    b. the Pfizer mRNA COVID-19 vaccine is suitable for use in immunocompromised individuals. However, patients receiving the following therapies should get advice from their specialist before receiving the Pfizer mRNA COVID-19 vaccine: pembrolizumab (Keytruda), nivolumab (Opdivo), ipilimumab (Yervoy), atezolizumab (Tecentriq);
    c. the Pfizer mRNA COVID-19 vaccine is suitable for use in pregnancy. However, as there is currently no data on outcomes in pregnant women, they should discuss the risks and benefits of receiving the Pfizer mRNA COVID-19 vaccine with a health professional;

[1] If there is outbreak in some settings (e.g., a school), vaccination of children under 16 years may need to be considered.

d. the Pfizer mRNA COVID-19 vaccine is suitable for use in lactating women;

e. people with a history of anaphylaxis to any previous Pfizer mRNA COVID-19 vaccine or any component of the vaccine should not receive a Pfizer mRNA COVID-19 vaccine;

f. because of the rare potential for severe allergic reactions (anaphylaxis), it is recommended that all subjects be observed for 30 minutes after the vaccine has been administered;

g. people with a history of any immediate allergic reaction to other vaccines or any products may be vaccinated but this should be done in a health care setting, where, in the unlikely event of a reaction, it can be immediately treated with adrenaline.

5. The group noted that given the relatively high prevalence of common side effects with the Pfizer mRNA COVID-19 vaccine, it is important that all recipients should receive information about expected responses (e.g., fever, muscle pain, fatigue), how to manage these (e.g., analgesia) and who to call for advice if these reactions become problematic. Such reactions are more frequent after administration of the second dose (patient information may need to be adjusted).

Appendix One: Medsafe provisional consent – clinical aspects

6. The CV TAG noted Medsafe's proposed conditions relating to the clinical aspects of the Pfizer vaccine (BNT162b2). Conditions include:

    a. Provide any reports on the duration of efficacy and the requirement for booster doses within five working days of these being produced.

    b. Provide the six months analysis data from Study C4591001. Report due: April 2021.

    c. Provide any reports on efficacy including asymptomatic infection in the vaccinated group, vaccine failure, immunogenicity, efficacy in population subgroups and results from post-marketing studies, within five working days of these being produced.

    d. Provide the final Clinical Study Reports for Study C4591001 and Study BNT162-01 within five working days of these being produced.

    e. Provide Periodic Safety Update Reports according to the same schedule as required by the European Medicines Agency.

    f. Provide monthly safety reports, as well as all safety reviews they conduct or become aware of.

    g. Perform the required pharmacovigilance activities and interventions detailed in the agreed Risk Management Plan (RMP) and any agreed updates to the RMP. An RMP should be submitted at the request of Medsafe or whenever the risk management system is modified, especially as the result of new information being received that may lead to a significant change to the benefit/risk profile or as the result of an important milestone being reached.