Australian Government

COVID-19 VACCINATION

Phase 1B General Practice Vaccine Rollout

Update – 8 April, 2021

Updated ATAGI advice on AstraZeneca vaccine

The Government has asked ATAGI and the TGA to immediately consider and advise on the latest vaccination findings out of Europe and the UK.

Talking points:

- The Australian Government is following events in Europe and UK closely and has asked ATAGI and the TGA to immediately consider and advise on these latest vaccination findings.
- The Australian Government places safety above all else, as it has done throughout the pandemic, and will continue to follow the medical advice in protecting Australians.
- The European regulatory agency has stated that a causal relationship between vaccination and the occurrence of thrombosis in combination with thrombocytopenia is considered plausible.
- These are extremely rare events, though. It is a very safe, very effective vaccine in most cases.
- Australian officials are talking with the WHO, UK, European and other regulatory agencies in countries where the use of AstraZeneca vaccine has been widespread.
- Regulators have already been working with their international counterparts to consider the latest international evidence.
- ATAGI met for several hours yesterday and will be meeting again today. We do not want to pre-empt the advice of the medical expert panel.
- These recommendations will continue to be reviewed on a regular basis and may be revised as more evidence becomes available, particularly those that may potentially change the benefit-risk balance or better define risk factors for this condition.
- The system is working. We know that it is very important to follow particularly for new vaccines like the COVID-19 vaccines as they are rolled out to millions of people in the world. And picking up rare side effects, investigating them, working through any particular warnings that need to come out – these events are all crucial.

- Advice will be provided to the Commonwealth Government for immediate consideration and relayed to AHPPC which is the Medical Expert Panel led by the Chief Medical Officer and also comprising all State and Territory Chief Health Officers.

- The matter will also be discussed with States and Territories through the States and Territories Health Ministers Meeting and the National Cabinet.

- In Australia, the Therapeutic Goods Administration's (TGA) Vaccine Safety Investigation Group have assessed a person with thrombosis and thrombocytopenia admitted to a Melbourne hospital. This occurred after they received the AstraZeneca COVID-19 vaccine.

- The Vaccine Safety Investigation Group concludes this is a new syndrome and is likely linked to the AstraZeneca COVID-19 vaccine. The exact cause is being investigated through ongoing studies around the world. Further work is required to determine a definitive outcome.

- The Department is further developing and refining resources for informed consent that clearly convey the benefits and risks of vaccination for both providers and consumers.

New information and updates will be shared as soon as it becomes available.

Sources of Communication

Vaccination sites are recommended to add the below email addresses to their safe senders list as they may be used to send important communications about the COVID-19 Vaccination Program:

- no-reply@cvas-mail.health.gov.au
- No-Reply.Vaccine@Health.gov.au

Issue: Advice on drawing up the AstraZeneca vaccine prior to administration

Response:

The Advice on drawing up the AstraZeneca COVID-19 vaccine prior to administration has been updated to reflect new information in the AstraZeneca COVID-19 vaccine product information (PI) and now contains the following explanatory statement:

> Although there are data supporting stability of vaccine doses after withdrawal into a syringe for up to 6 hours at room temperature (as reflected in the Astra Zeneca vaccine product information [PI]), ATAGI recommends that, as much as possible, pre-drawn doses be used within an hour in order to minimise any remote potential risk of infection.

Please note that the overall recommendations and intent of guidance remains the same.

Updated documents and statements on health.gov.au over Easter: AstraZeneca vaccine

Provider guide for obtaining informed consent:

https://www.health.gov.au/resources/publications/covid-19-vaccination-atagi-immunisation-provider-guide-to-obtaining-informed-consent-for-covid-19-vaccine

Consent form for COVID-19 vaccination:

https://www.health.gov.au/resources/publications/covid-19-vaccination-consent-form-for-covid-19-vaccination

Consumer information on the AstraZeneca vaccine:

https://www.health.gov.au/resources/publications/covid-19-vaccination-information-on-covid-19-astrazeneca-vaccine

Information for after your AstraZeneca vaccine:

https://www.health.gov.au/resources/publications/covid-19-vaccination-after-your-astrazeneca-vaccine

See here also a range of statements recently published on the health website:

Joint statement from acting Australian Government Chief Medical Officer, Professor Michael Kidd and Head of the Therapeutic Goods Administration Adj. Professor John Skerritt:

https://health.gov.au/news/joint-statement-on-astrazeneca-covid-19-vaccine

Updated ATAGI statement for healthcare providers:

https://health.gov.au/news/atagi-statement-healthcare-providers-specific-clotting-condition-reported-after-covid-19-vaccination

ATAGI statement for consumers:

https://health.gov.au/news/atagi-statement-consumers-specific-clotting-condition-after-covid-19-vaccination

TGA statement:

https://www.tga.gov.au/media-release/specific-clotting-condition-reported-after-covid-19-vaccination

Additional statement from ATAGI:

https://health.gov.au/news/atagi-statement-covid-19-vaccination-reported-case-of-thrombosis