



## Australian Government

### Department of Health

Dear Australian COVID-19 Vaccine Delivery Partner

By now you will be aware of advice provided by the Australian Technical Advisory Group on Immunisation (ATAGI) in light of the evolving evidence of a rare but serious side effect involving thrombosis with thrombocytopenia following receipt of the AstraZeneca vaccine.

This 'thrombosis with thrombocytopenia syndrome' (TTS) is a newly described serious condition, with unusual blood clots in the brain (cerebral venous sinus thrombosis) or in other parts of the body, associated with low platelet levels and can cause serious long term disability or death.

The evidence that connects TTS to receipt of the AstraZeneca vaccine has been reviewed by ATAGI and the Therapeutic Goods Administration (TGA) and subsequently, ATAGI has

recommended new changes to the Australian COVID-19 Vaccine Program including a **preference for the use of the Comirnaty (Pfizer) vaccine in adults aged under 50 years.**

The ATAGI statement (found [here](#)) provides further information on the key considerations that went into formulating this advice. Amongst these were the following:

- TTS remains an extremely rare event among vaccine recipients. Experience in Europe has shown approximately 4 – 6 people in every one million people develop TTS in the 4-20 days after the first dose of vaccine. However higher rates have been reported in some countries, and among younger people. One person in Australia developed the syndrome after receiving the AstraZeneca vaccine.
- While Australia currently has very low or no community transmission of COVID-19, this could change. The risk of serious disease and death in Australia remains, even as border controls and other measures continue.
- The individual benefit-to-risk balance of vaccination with COVID-19 vaccine AstraZeneca in Australia varies with age. The risk of ongoing health issues and death from COVID-19 is highest in older age groups, particularly rising from 50 years of age. By comparison, the rate, and so possibility of disability and death from TTS may be higher in younger people.

Please note that ATAGI has further recommended that:

- The **AstraZeneca vaccine should only be used in adults aged under 50 where the benefits clearly outweigh the risk** for that individual and the person has made an informed decision based on an understanding of the risks and benefits.
- **People who have had the first dose of COVID-19 Vaccine AstraZeneca without any serious adverse effects can be given the second dose, including adults under 50 years.**

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. On this basis, the Government has accepted ATAGI's recommendations and will move swiftly to ensure Australia's vaccination program and advice to patients is adjusted accordingly, as per the [TGA's](#) and [Department of Health Secretary and Chief Medical Officer](#) statements.

In the short term, and **in line with ATAGI's recommendations, you may want to contact any patients under 50 who are currently booked to receive their first dose of the AstraZeneca**

### **COVID-19 vaccine and cancel in cases where the benefit clearly does not outweigh the risk.**

As per the previous ATAGI statement on 2 April (found [here](#)), please remain alert for warning signs of TTS in those who have received the AstraZeneca COVID-19 vaccine. So far these have included as either central venous sinus thrombosis (CVST) or thrombosis in other sites, such as intra-abdominal venous systems. These presentations have occurred between 4 and 20 days following receipt of the AstraZeneca COVID-19 vaccine. CVST may present as a new onset persistent headache not settling with analgesia, features of raised intracranial pressure (including acute severe headache, vomiting, confusion), focal neurological deficits, and/or seizures. Thrombosis in the intra-abdominal venous system may present as abdominal pain.

I appreciate that this change in direction is sudden, and may cause additional stress and difficulty over the next period. It is also likely to contribute to an increase in vaccine hesitancy amongst your patients. GPs are key to managing this risk in their roles as trusted advisors, and we expect that you will be called upon to assist your patients to make an informed decision based on their individual circumstances. I suggest you reiterate to your patients:

- the risk of developing this side-effect following receipt of the AstraZeneca vaccine is extremely rare;
- the new age-based recommendations are made out of an abundance of caution and the benefits of the COVID-19 AstraZeneca vaccination outweigh the risks for the vast majority of people; and
- that if you have received your first dose of the vaccine with no major adverse reaction, you are strongly encouraged to receive the second dose as planned.

If you have questions about specific patients with prior medical conditions, you can contact the [specialist immunisation service](#) within your jurisdiction.

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, and we will continue to provide you with advice and patient resources in coming days and will be sent directly to you. The attached script has also been developed to assist your practice to respond to patients who may call with questions about the AstraZeneca vaccine. Please continue to check [www.health.gov.au](http://www.health.gov.au) for the most up to date information.

ATAGI and the TGA will continue to review the evidence on a regular basis, and as with everything during this pandemic, it is possible that there may be further changes to this advice as new evidence emerges or the epidemiological situation changes. The Department will be working with states and territories to determine how those under the age of 50 in phase 1 can access the Pfizer (Cominarty) vaccine in a timely fashion. We will keep you updated with this process as it continues, and will come back in coming days with further resources and information.

I want to take this opportunity to again thank you for your flexibility, commitment and resilience during the pandemic.

**Prof Paul Kelly MBBS, DTM+H, PhD, FAFPHM**  
**Chief Medical Officer**

Australian Government Department of Health

*The Department of Health acknowledges the Traditional Custodians of Australia and their continued connection to land, sea and community. We pay our respects to all Elders past and present.*