



Australian Government
Department of Health

Australian Technical Advisory Group on Immunisation

Australian Technical Advisory Group on Immunisation Submission to the Commonwealth Government COVID-19 Response Inquiry

Dear Panel Members,

The Australian Technical Advisory Group on Immunisation (ATAGI) is pleased to support the Commonwealth Government COVID-19 Response Inquiry (the Inquiry).

Additional input or information into vaccine related issues not covered by this submission can be provided on request. It should be noted ATAGI cannot disclose specific details of meeting discussions, nor information regarding decisions of Government or programmatic matters that rest outside the scope of the ATAGI role.

This is the only submission provided by ATAGI to the Inquiry and has been co-signed by the current ATAGI Chair and Deputy Chair, as well as former ATAGI Co-Chairs.

ATAGI terms of reference and membership

ATAGI advises the Minister for Health and Aged Care (the Minister) on the administration of vaccines available in Australia, including those available through National Immunisation Program, COVID-19 vaccines and other emerging issues, including responding to local transmission of Japanese Encephalitis and mpox.

ATAGI is also tasked with consulting with relevant organisations to produce the [Australian Immunisation Handbook](#) for approval by the National Health and Medical Research Council and in implementing immunisation policies, procedures and vaccine safety.

ATAGI membership represents a broad range of expertise, including clinical professionals, vaccine and immunisation researchers, epidemiologists and/or immunisation service delivery expertise, who possess in-depth knowledge of vaccines, immunisation and/or service delivery (e.g., immunisation program management).

ATAGI currently comprises 15 standing voting members, including a Chair and Deputy Chair, and 4 ex officio members. Voting members are appointed by the Minister for overlapping terms of four years. Details of the ATAGI membership structure along with the membership list and relevant expertise is published on the [Department of Health and Aged Care website](#).

In the early stages of the COVID-19 pandemic, ATAGI was monitoring COVID-19 vaccine candidates. In September 2020, the Department of Health and Aged Care (the Department) and ATAGI established the ATAGI COVID-19 Working Group (the Working Group), a subcommittee of ATAGI to provide specific advice on COVID-19 vaccines, in recognition of the volume and time sensitive nature of the work required from the ATAGI to support the Minister and the Department.

The aim of the Working Group was to provide timely advice to the Government on the appropriate, effective and equitable use of COVID-19 vaccines available in Australia. The membership of the Working Group included both ATAGI members and external experts and consisted of an Executive Group, and three subgroups focused on:

1. vaccine utilisation and prioritisation
2. vaccine distribution and program implementation; and
3. vaccine safety, evaluation, monitoring and confidence.

ATAGI remained responsive to the changing nature of the pandemic and in 2022, the structure was updated, with the Executive Group remaining in place and the three subgroups consolidated into a Working Group and a Safety Group. Finally, in 2023, the ATAGI COVID-19 Working Groups ceased operation, and work relating to COVID-19 was absorbed back into the ATAGI 'business as usual' meeting cadence.

ATAGI's role in the COVID-19 pandemic

During the global COVID-19 pandemic, the Department identified ATAGI as the appropriate advisory body for development of evidence-based advice on immunisation policies and use of COVID-19 vaccines in Australia reporting to the Minister. ATAGI's role was closely linked with regulatory and programmatic decisions of government that were made with input from a range of advisory groups including ATAGI, the Advisory Committee for Vaccines and the Scientific and Industry Technical Advisory Group.

ATAGI advice on COVID-19 vaccines and their use throughout the pandemic has been evidence-based, reflecting the best available and emerging data relating to vaccines, including safety, efficacy data from clinical trials, real-world effectiveness data, data on waning of immunity and local and international epidemiology. Where the rapidly evolving COVID-19 landscape resulted in limited evidence, ATAGI's decision making was informed by both the range of technical expertise across the committee and its networks in the broader scientific community. ATAGI met with experts in other countries, including equivalent National Immunisation Technical Advisory Groups (NITAGs) from the United Kingdom, Canada, Israel and the United States, drawing on safety and efficacy data accumulated from international programs. As such, the advice provided by ATAGI was informed by numerous data sources and relied on the best information available at the time when making recommendations to the Minister.

Due to the rapidly evolving environment and changes to vaccine products and availability, there was a need to communicate updated advice to the public quickly. Previously established pathways and processes for communicating vaccine advice and any updates, such as through via annual statements, public consultation, and publication in the Australian Immunisation Handbook (AIH), were not fit for purpose in this emergency period.

As such, processes were adapted, with advice from ATAGI relating to eligibility and administration of COVID-19 vaccines provided to the Minister, then published on the health.gov.au website, often with supporting rationale for specific decisions, in order to provide confidence in the vaccine program and assure the public that decisions were based on expert recommendations. This was a significant pivot in ATAGI's role, where previously much of their work had been undertaken in relative anonymity, despite having been established in 1997. This change in process was useful in responding to the evolving evidence and epidemiology, and corresponding changes in vaccine formulations. Having reached a more stable point in terms of the types of vaccines available and their use, the COVID-19 recommendations have been included in the AIH since 5 October 2023.

Summary of key events

During the COVID-19 pandemic phase from September 2020 until February 2023, the ATAGI COVID-19 Working Group and subcommittees held over 312 meetings and published 45 COVID-19 recommendations. ATAGI also published a significant number of supplementary statements for the public and immunisation providers and regular updates to provide greater transparency on their deliberations. Published recommendations varied in content between types of vaccines recommended for use, eligibility for different types of vaccines, updated advice regarding vaccine intervals, recommendations for at-risk populations, advice focused on safety matters, and a range of clinical guidance.

In 2023, six ATAGI COVID-19 statements have been published and 12 ATAGI meetings held, three of which were face to face.

ATAGI attempted to respond in a flexible and agile way, acknowledging that rapid decisions were required in the setting of significant uncertainty. ATAGI also understood that decisions made were likely to significantly shape the national COVID-19 response and public confidence in immunisation. ATAGI actively consulted with a range of stakeholders including the TGA, the National Health and Medical Research Council COVID-19 forum and other groups including the Aboriginal and Torres Strait Islander Advisory Group on COVID-19 and the COVID-19 Disability Advisory Committee and the AHPPC Aged Care Advisory Group.

ATAGI closely monitored the progress of COVID-19 vaccine programs worldwide, drawing on NITAG networks and real-world data to rapidly respond to safety issues that occurred during the rollout. Through this monitoring and engagement, ATAGI was able to identify and respond to extremely rare, but serious, adverse events following immunisation including thrombosis with thrombocytopenia syndrome (TTS), and myocarditis/pericarditis.

In March 2021, ATAGI published several statements following reports from international counterparts of TTS following use of the AstraZeneca vaccine in the United Kingdom and Europe. ATAGI then met urgently following the first reported case in Australia and, over the subsequent months, met weekly to consider the evolving understanding of the pathogenesis and epidemiology of TTS and the risk at that time in the context of COVID-19 infection and transmission. This included consulting with the TGA and local and international experts and updating the available advice in line with the latest information.

This advice was developed in the context of significant uncertainty and rapidly emerging evidence. For example, early advice regarding TTS required in the early stages of the rollout of the vaccination program and evolving supply landscape, when there were very few cases of COVID in the community but the likelihood of ongoing control was uncertain, and where there was significant variation in the risk estimates of TTS reported in other countries that had deployed the AstraZeneca vaccine. There was also emerging evidence that early identification of TTS cases improved outcomes, so ATAGI continued to have close engagement with expert haematologist colleagues, to provide advice regarding the clinical identification and management of cases, which were collated and reported on publicly by the TGA, who attend ATAGI meetings in an ex-officio capacity.

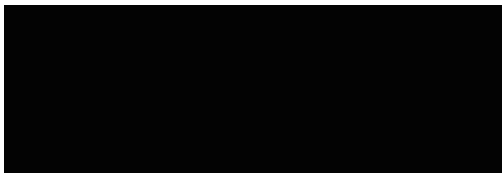
Further to their work on TTS, ATAGI received the first indications of possible cases of myocarditis following COVID-19 vaccines towards the end of June 2021, initially via reports from the USA and Israel. In response to this, in early July 2021 ATAGI experts, together with cardiologists, met to consider all available evidence including data collected by the TGA who thoroughly assesses and undertake continual monitoring of safety, quality and effectiveness of all vaccines.

The *ATAGI Guidance on Myocarditis and Pericarditis following COVID-19 vaccination* was developed in consultation with cardiologists and other medical experts and published on 2 August 2021. Myocarditis and pericarditis are rare adverse events associated with COVID-19 vaccines. However, myopericarditis can also occur following COVID-19, or may be unrelated to vaccine or COVID-19, with ATAGI advice providing a risk-benefit summary which varies by age of the vaccine recipient.

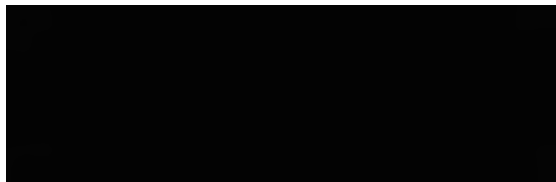
More recently ATAGI has provided advice on both new variant COVID-19 vaccines, both the bivalent and monovalent, with a continued focus on those at risk of severe disease, which includes age (e.g. 75 years and older) and underlying medical conditions, including significant immunosuppression. ATAGI remains committed to providing quality, evidence-based advice on the use of vaccines to support the Minister for Health and Aged Care and the Australian community.

ATAGI would welcome opportunities to provide further input to the Inquiry on the role and activities undertaken throughout the COVID-19 pandemic, as well as lessons learned to improve pandemic preparedness and responses in the future.

Yours sincerely,



Prof Nigel Crawford
Chair



Prof Michelle Giles
Deputy Chair



Prof Allen Cheng
Former ATAGI Co-Chair



Prof Christopher Blyth
Former ATAGI Co-Chair

20 December 2023