

**Policies and procedures for the
administration and governance of the
Australian Technical Advisory Group on Immunisation**

Effective 1 July 2019

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1. Introduction

The Australian Technical Advisory Group on Immunisation (ATAGI) is a ministerially appointed advisory group, comprised of representatives with a mix of research, clinical and implementation expertise. ATAGI's purpose is to provide evidence based advice on immunisation policies, programs and priorities to the Australian Government Minister for Health.

ATAGI develops evidence-based recommendations for the approval of the National Health and Medical Research Council (NHMRC) through the formulation of the Australian Immunisation Handbook. To inform this advice, ATAGI considers the epidemiology of diseases, burden of disease, vaccine efficacy and effectiveness, vaccine safety and implementation issues.

ATAGI also provides advice to the Pharmaceutical Benefits Advisory Committee (PBAC) and to pharmaceutical companies on the clinical effectiveness of vaccines for being considered for use as part of population programs through the National Immunisation Program (NIP).

2. About this document

This document is intended to outline for ATAGI members and for interested members of the general public, ATAGI's structure, function, roles and responsibilities.

3. ATAGI's purpose

To provide evidence based advice on immunisation policies, programs and priorities to the Minister for Health.

4. ATAGI's role

ATAGI's role is to:

- Provide technical input to policy development through epidemiological reviews, promotion of research, and assessment of the evidence for vaccination programs.
- Provide advice to the PBAC in fulfilling its functions as set out in the *National Health Act 1953* with respect to vaccines.
- Produce the Australian Immunisation Handbook, meeting requirements set out by the NHMRC.
- Provide technical advice to support effective implementation and communication of the NIP.
- Identify knowledge gaps and provide advice to national funding bodies on priorities for research to inform immunisation policy.
- Engage internationally through multilateral forums and with other National Immunisation Technical Advisory Groups.
- Provide advice to the Minister for Health and the Australian Government Department of Health on matters relating to immunisation, for example vaccine safety and the utilisation of vaccines to ensure effective disease control through the National Immunisation Program.

ATAGI undertakes this role with technical support from the:

- National Centre for Immunisation Research and Surveillance (NCIRS), which is ATAGI's Technical Secretariat particularly focused on the Australian Immunisation Handbook, for policy advice to Government, and ATAGI's publications and statements; and
- vaccine evaluation groups, which provide technical support for the development of advices to the PBAC and companies.

5. Engagement with industry and stakeholders

Engagement with industry and stakeholders is critical for ensuring ATAGI has access to the most contemporary information regarding vaccines and also is able to consider the breadth of stakeholder views.

To this end, ATAGI will host a commercial-in-confidence Industry Day each year (expected in May), to enable engagement with pharmaceutical companies on the latest developments in vaccines and to enable horizon scanning and future planning.

In addition, ATAGI will host a confidential Stakeholder Day each year (expected in August), to enable engagement with key professional groups (e.g. medical colleges) on key immunisation issues.

Participation in Industry Day and Stakeholder Day will be managed through the ATAGI Administrative Secretariat.

6. ATAGI publications and statements

ATAGI will review and update the Australian Immunisation Handbook on an ongoing basis, to account for emerging evidence and new vaccines.

Each year ATAGI will publish an evidence based statement on vaccine preventable diseases, titled the ATAGI Annual Statement on Immunisation, to cover key trends and issues in the epidemiology and control of vaccine preventable diseases in Australia. The Australian Government Chief Medical Officer will endorse these statements ahead of publication.

ATAGI will publish epidemiological review/s and/or statement/s each year, focused on key diseases of interest, disseminating evidence based information on emerging and challenging vaccine preventable issues.

ATAGI will publish clinical statements to support implementation of changes to the NIP and address issues of concern (e.g. vaccine availability), as required.

ATAGI posts agendas at least 4 weeks in advance of meetings and publishes Bulletins summarising outcomes at least 6 weeks after the meeting.

7. ATAGI structure

ATAGI comprises a Chair, Deputy Chair and Members. ATAGI reports to the Australian Government Minister for Health, directly or through the Australian Government Department of Health.

8. ATAGI members

ATAGI comprises 15 standing voting members (including a Chair and Deputy Chair) and 4 ex officio members.

Temporary members are able to be appointed on a short term basis by the Australian Government Chief Medical Officer, including at the request of the Chair of ATAGI to provide specific expertise on key topics. Temporary members will be voting members for the term of their appointment to ATAGI.

Where possible, cross membership will be sought with other relevant Australian Government committees (e.g. the Advisory Committee on Vaccines).

8.1 Voting members

Voting members serve overlapping terms of up to 4 years. While there are no limits to terms, it is anticipated that new members will continue to be appointed to ATAGI to ensure new skills and experiences are brought to the Group.

Expressions of interest to participate as a voting member are called to enable a short list to be developed by the Australian Government Chief Medical Officer for consideration by the Australian Government Minister for Health.

Appointments are made by the Minister for Health and remuneration approved by the Australian Government Remuneration Tribunal.

Voting members fall into two categories: clinical professionals, researchers and/or service delivery experts; and consumer representatives.

8.1.1 Clinical professionals, researchers, and/or service delivery experts

Up to 14 individuals including clinical professionals, vaccine and immunisation researchers, and/or immunisation service delivery expertise, who possess in-depth knowledge of vaccines, immunisation and/or service delivery (e.g. immunisation program management).

Clinical professionals bring expertise in areas such as paediatrics, immunology, infectious diseases (paediatric and adult), public health, immunosuppression in adults, maternal immunisation, and pathology.

Researchers bring experience in disciplines supporting the assessment of vaccines and their use in the population, including epidemiology, modelling of infectious diseases, the behavioural factors impacting vaccine uptake, health technology assessment, and systematic reviews of evidence.

Immunisation service delivery experts bring experience in General Practice, nurse immunisation, immunisation for Aboriginal and Torres Strait Islander peoples, and immunisation for Culturally and Linguistically Diverse populations.

8.1.2 Consumer representative

At least one Voting member must be a consumer representative, who is a technically qualified person knowledgeable about consumer perspectives and/or the social and community aspects of immunisation programs.

8.2 Ex officio members

Up to 6 members are ex officio, representing key partners and organisations required to support the effective delivery of immunisation in Australia.

NCIRS is represented by the Director of the Centre, whose role is to oversee the provision of the ATAGI Technical Secretariat, including for critical assessment of new and emerging trends, assessment of the impact of vaccination programs, and technical development of the Australian Immunisation Handbook.

The Communicable Diseases Network Australia (CDNA) is represented by a nominated member whose role is to provide advice on surveillance, monitoring and the control of vaccine preventable diseases.

The Australian Government Department of Health's Office of Health Protection is represented by the Assistant Secretary, Immunisation Branch, whose role is to provide advice on implementation issues for the NIP and to support engagement with other committees and Divisions within Health. The Assistant Secretary, Immunisation Branch is also responsible for providing administrative support for ATAGI.

The Therapeutic Goods Administration is represented by the Assistant Secretary, Pharmacovigilance and Special Access Branch, whose role is to provide advice on vaccine safety issues and to support engagement between other Divisions and the Therapeutic Goods Administration.

A member of the PBAC or its sub-committees may be appointed to ATAGI on the recommendation of the Chair of the Pharmaceutical Benefits Advisory Committee.

A member of the National Immunisation Committee may be appointed to ATAGI.

Ex officio roles are agreed by the Minister for Health and appointment is delegated to the First Assistant Secretary of the Office of Health Protection (OHP).

8.3 Member roles and responsibilities

Members are responsible for attending and participating in all ATAGI meetings and for contributing to out-of-session discussions and items.

Members will engage with Vaccine Evaluation Groups to support the development of pre-submission advice to the PBAC and companies.

Members will engage with NCIRS to support development of recommendations for the Australian Immunisation Handbook, policy advice to Government and relevant publications.

Before meetings, members are required to prepare by reading and commenting on relevant ATAGI papers.

Members are responsible for reporting any Declarations of Interest prior to meetings that are published on the immunisation website.

In addition, members must also provide timely provision of expenditure forms after meetings to ensure that members can be paid in line with the Remuneration Tribunal Determination.

9. Declarations of interest

Applicants to ATAGI are required to submit a *Declaration of Interests (Dols)* form to enable consideration of potential or perceived conflicts of interest as part of the ATAGI selection process.

Ahead of each ATAGI meeting, members are required to submit DoI, which are reviewed by the ATAGI Chair, consumer representative/s and the Department. Through this process, declarations are used to determine the member's participation in the upcoming and subsequent meetings, including: exclusion from discussions (category A); participation but not final endorsement of decisions (category B); or transparency (category C).

The ATAGI members DoI and their determinations are distributed to all members as part of the ATAGI meeting papers to provide all members an opportunity to review and query determinations made by the Chair, consumer representative/s and the Department. A summary of ATAGI members DoI's are published in minutes of each meeting and available on the Department website at <https://beta.health.gov.au/committees-and-groups/australian-technical-advisory-group-on-immunisation>

10. ATAGI leadership

10.1 Chair and Deputy Chair appointments

Every three years, the Minister for Health appoints an ATAGI Chair from the ATAGI members who have served at least one year. In addition, the Minister for Health also appoints a Deputy Chair, able to act as the Chair in the absence of the Chair and to undertake additional duties as required.

The Minister may appoint ATAGI co-Chairs instead of a Chair and Deputy Chair.

In making these decisions, the Minister for Health considers the member's leadership skills, knowledge and experience in vaccination and immunisation, ability to represent ATAGI at national and international meetings, and capacity to engage effectively with relevant stakeholders, capacity to manage meetings, and their availability to meet the requirements of the role.

Each member is able to serve two terms (i.e. six years) as the Deputy Chair and two terms as the Chair.

10.2 Chair's role

The role of the Chair is to:

- Lead ATAGI in supporting the Minister for Health, including setting ATAGI's strategic directions and agenda in collaboration with the Department of Health.
- Providing leadership and ensuring committee members are aware of their obligations and that the committee complies with its responsibilities.
- Seek and review conflicts of interests from members, along with the Consumer Representative and the Assistant Secretary, Immunisation Branch.

- Lead meetings, including setting the agenda and ensuring decisions are clear and accountable.
- Action decisions made by ATAGI, by authorising correspondence and documentation.
- Leads engagement with industry and stakeholder groups, including managing Industry Day and Stakeholder Day.
- Representing ATAGI at PBAC meetings, with the media and at national and international events, or nominating a suitable delegate, when required or as appropriate.

10.3 Deputy Chair's role

- The ATAGI Chair may call upon the Deputy Chair to assist with any of the Chair's roles and responsibilities as required.

11. ATAGI decision making

ATAGI voting members are required to make an effort to reach a consensus on issues discussed.

The quorum for decision making is a simple majority of voting members, i.e. a number greater than 50% of the number of ATAGI voting members.

Members are required to vote in circumstances where no consensus is reached.

The ATAGI Chair has the casting vote in circumstances where the vote is tied.

12. ATAGI Secretariat

The ATAGI Secretariat is comprised of Australian Government Department of Health staff.

The Assistant Secretary, Immunisation Branch oversees the administrative arrangements for ATAGI, noting day to day management and coordination through the Director of the Immunisation Policy Section, Immunisation Branch.

The ATAGI Secretariat is responsible for the organisation and coordination of all ATAGI meetings including the preparation and coordination of ATAGI agendas, agenda papers, minutes and bulletins.

The ATAGI Secretariat is also responsible for the administration and processing of requests from pharmaceutical companies for pre-submission advice from ATAGI to inform submissions to the PBAC for listing of vaccines on the NIP.

The ATAGI Secretariat can be contacted through its email address: ATAGI.Secretariat@health.gov.au

13. ATAGI Meetings

Regularly scheduled meetings are held six times a year, four of which are face to face, two of which are conducted via videoconference.

Face to face meetings occur in February, May, August and December. Videoconferences are held in June and October.

Meeting dates are announced at least 12 months in advance (with the exception of extraordinary meetings) and are posted on ATAGI's home page. Face to face meetings are generally held in Canberra, ACT.

Should additional meetings be required outside of this schedule, in a face-to-face, videoconference or teleconference capacity, these are determined through consultation between the Department and the ATAGI Chair.

14. Remuneration

Remuneration for the committee members is in accordance with the principles and rates set by the Remuneration Tribunal in its Determination: Remuneration and Allowances for Holders of Part-time Public Office. The latest

version of the Determination can be accessed at the Remuneration Tribunal website:

<https://www.remtribunal.gov.au/>.

15. Funding ATAGI's work

The majority of ATAGI's funding comes from the Australian Government Department of Health – these funds are used to fund activities related to the Australian Immunisation Handbook and the development of policy advice.

In addition, the Australian Government funds NCIRS to provide technical support to ATAGI.

Some funding is provided by pharmaceutical companies on a cost recovery basis for the provision of advice to support submissions to the Pharmaceutical Benefits Advisory Committee, consistent with the Australian Government Cost Recovery Framework.

16. Media engagement

Members are free to give interviews and their opinions, or views of their employer or professional organisation.

If requested to speak on behalf of ATAGI, members are required to seek approval from the Australian Government Department of Health via the ATAGI Secretariat.

Requests from news agencies are to be made via the ATAGI Secretariat.

17. Correspondence

All correspondence to ATAGI should be directed to the ATAGI Secretariat at ATAGI.Secretariat@health.gov.au.

18. Relevant links and information

- Australian Government Department of Health website: <https://beta.health.gov.au/health-topics/immunisation>
- The Australian Immunisation Handbook: <https://immunisationhandbook.health.gov.au/>
- Pharmaceutical Benefits Advisory Committee: <http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings>
- Procedure guidance for obtaining ATAGI advice for new vaccines for the National Immunisation Program: [forthcoming]
- National Health and Medical Research Council: <https://nhmrc.gov.au/>