Procedures for Australian Technical Advisory Group on Immunisation (ATAGI) advice to the Pharmaceutical Benefits Advisory Committee (PBAC)

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Title: Procedures for Australian Technical Advisory Group on Immunisation (ATAGI) advice to the Pharmaceutical Benefits Advisory Committee (PBAC)

Contents

Record of updates

Date	Version	Summary of changes
Oct2018	Version 1.0	Draft procedure guidance released.
Dec 2018	Version 2.0	Incorporate feedback from workshop day 30/11/18
Feb 2019	Version 3.0	Finalise documents for delivery

Shortened forms and definitions

Acronyms and abbreviations

Term	Definition
ATAGI	Australian Technical Advisory Group on Immunisation
Department	Australian Government Department of Health
ESC	Economics Sub-Committee
HTA	health technology assessment
NIP	National Immunisation Program
OHTA	Office of Health Technology Assessment
PICO	Population, Intervention, Comparator, Outcome
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefits Scheme
TGA	Therapeutic Goods Administration

Definitions

Sponsor

The sponsor of a submission seeking listing on the National Immunisation Program or PBS. 'Sponsor' is used interchangeably for the following – a pharmaceutical company sponsoring the TGA application or marketing the product in Australia, or an organisation or individual supporting the preparation of a submission. Sponsors are also referred to as responsible persons in the *National Health Act 1953*and Regulations in relation to price agreements and listed products.

Vaccine

According to the World Health Organisation, a vaccine "is a biological preparation that improves immunity to a particular disease. A vaccine typically contains an agent that resembles a disease-causing microorganism, and is often made from weakened or killed forms of the microbe, its toxins or one of its surface proteins. The agent stimulates the body's immune system to recognize the agent as foreign, destroy it, and "remember" it, so that the immune system can more easily recognize and destroy any of these microorganisms that it later encounters." (http://www.who.int/topics/vaccines/en/)

1 Purpose

This procedure guidance describes the processes that are undertaken by sponsors, the Australian Technical Advisory Group on Immunisation (ATAGI), external Vaccine Evaluation Groups, and the Department of Health when considering and listing vaccines on the National Immunisation Program (NIP) and the Pharmaceutical Benefits Scheme (PBS). It provides information to sponsors on processes, procedures, timelines and documents required.

This procedure guidance is an accompanying document to the *Procedure guidance for listing medicines on the Pharmaceutical Benefits Scheme*, and the *Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee*. It should be used in conjunction with the *Guidelines for preparing a request for advice from the Australian Technical Advisory Group on Immunisation (ATAGI) to support Pharmaceutical Benefits Advisory Committee (PBAC) consideration of vaccines*.

This document explains:

- The requirements from sponsors when seeking ATAGI advice on their submissions;
- The process by which the ATAGI advice is developed; and,
- What sponsors can expect from ATAGI and the timeframe in which advice will be provided.

This document is maintained by the Department of Health. The document is routinely revised in response to changes to the processes involved in consideration and listing of vaccines on the NIP.

Any comments or questions of a general nature about the topics included in the guidance, accuracy of the content or other matters should be forwarded to the department (refer to Appendix A).

2 ATAGI advice process

The process for requests for ATAGI advice (pre- PBAC submission) is represented in the timeline below. Major stages are highlighted and minor stages are italicised.

A preliminary meeting is available to sponsors prior to deciding to submit, to ensure that the proposed vaccine is suitable for the NIP. Once a positive response is received, sponsors can proceed with the *Request for ATAGI advice*.

The provision of ATAGI advice (pre-submission) broadly involves:

Notifying the department of an intention to request ATAGI advice

Producing the *Request for ATAGI Advice* following the guidance document

An external Vaccine Evaluation Group producing a draft advice document

ATAGI considering the draft advice, led by ATAGI discussants

ATAGI endorsing the advice and returning it to the sponsor and PBAC.

ATAGI also provide post-submission advice to PBAC where required. These stages are described in more detail in Chapter 4.

The timeframes provided in Figure 1 are relative to the PBAC meeting at which the submission will be considered by the PBAC. The actual calendar dates each year are published on the PBS website. Submissions generally need to be lodged by 4 pm on the specified days. Sponsors who need to lodge later than 4 pm should notify the department ahead of time (refer to contact details in Appendix A).

Requests for ATAGI advice will be assigned a unique identifier once the notification of intention to request advice is received. This identifier should be used on all subsequent correspondence with the Department.

The provision of ATAGI advice is cost-recoverable. The cost of the advice will vary based on whether the *Request for ATAGI Advice* is simple or complex. The ATAGI secretariat, in consultation with the ATAGI Chair, will determine if a request is simple or complex based on the *Request*. If the sponsor wishes to seek the simple request fee, adequate justification should be included in the request.

A simple request may include those where:

- The vaccine is an additional brand compared with one already on the National Health (Immunisation Program – Designated Vaccines) Determination, where head to head trial data are available with equivalent efficacy and safety outcomes as reported for currently listed brand
- The vaccine is already on the NIP and the submission represents a modification of existing cohort, e.g. change in age range for elderly; amendment to existing NIP administration point without implications for other vaccines; trial data from studies that use the same design and efficacy outcomes as for consideration of cohort as it was originally listed, data to show duration of immunological response/waning of immunity have previously been accepted.
- Where there is extended serogroup/type protection for an existing vaccine approved for use on the NIP, for example QIV to substitute for TIV (as long as no obvious difference in formulation/adjuvant composition between the two and non-inferiority of safety and efficacy/effectiveness against the shared antigen components can be demonstrated)
- New combination: components are already on the NIP (co-administered) and where clinical data include both interaction studies and head to head clinical trial data

A complex request may include those where:

- There is any superiority claim
- Any dynamic model involving new herd immunity assumptions not previously accepted by PBAC for this population.
- Substantially new target population group, including new target indication;
- High risk target group unless previously accepted by PBAC and head to head data from RCT are available
- Requests for more than one target population – or where multiple comparators apply – e.g., if request is for 'all adults' but the comparators are different according to the age range such that comparator is 'no vaccination' in 18-60 years but 'existing vaccine' in 60+ years.
- Any safety signal or concern, especially serious adverse events (SAEs), such as febrile seizures
- Where efficacy data are complex; data derived from multiple sources without head to head evidence
- If efficacy data are based on surrogate endpoints not previously accepted
- If key safety data for target populations are lacking
- If complicated by implementation issues such as school-based program such that options for best coverage need to be weighed against optimising the interval between doses (as with immunisation of year 10s for HPV vaccine).

The final determination of whether a request is simple or complex rests with the Department. Although the cost of ATAGI advice for a simple request is less than for a complex request, the timeframes are the same.

Re-submissions

In the event that a sponsor is considering a re-submission following a rejection by PBAC, updated advice may be requested from ATAGI (for example, in cases where some time has elapsed since the initial ATAGI/PBAC consideration). In deciding whether to request updated advice prior to a re-submission, the sponsor should consider:

- Do updated epidemiology figures show a substantial change in disease patterns or prevalence?
- Does the immunisation proposal include wide-ranging changes to dosing, booster or catch-up program?
- Has a new vaccine been added to the NIP which now constitutes a potential comparator?
- Has the treatment algorithm changed for management of the vaccine preventable disease?
- Have new clinical trial data been published or has a new safety signal emerged for vaccine adverse events?

If five or more years have elapsed since the previous ATAGI advice, a resubmission to PBAC should include (unless adequately justified) updated ATAGI advice as it is highly likely that more than one of these factors will have changed.

If the sponsor is in doubt whether to seek an update to the previous advice, the ATAGI Secretariat will make a final determination in consultation with ATAGI Chair.

In a request for updated ATAGI advice, the sponsor should include a table outlining all aspects that will change in the proposed re-submission and their impact compared to the previous submission.

Figure 1 Timeline of ATAGI procedures

Stage	Process	Product	Responsibility	*Timeline*
Preliminary meeting	Sponsor meets with Department (and ATAGI representative) to discuss intended vaccine application for potential suitability for NIP		Sponsor, ATAGI Secretariat, ATAGI	*on an as-needs basis, or as set by the Department*
pre-request	Sponsor notifies Department of intention to submit request for ATAGI advice		Sponsor	*At least 22 weeks before ATAGI meeting*
1	**Sponsor *Request for ATAGI advice* submitted to Department (ATAGI secretariat)**	*Request for ATAGI advice*, following guidelines	Sponsor	***20 weeks before ATAGI meeting***
1a	*Department handles contractual arrangements for draft ATAGI advice with external Vaccine Evaluation Group, and in consultation with ATAGI chair, assigns discussants and ensures Request is complete*		ATAGI Secretariat	***18 weeks before ATAGI meeting***
2	**Vaccine Evaluation Group prepares draft ATAGI advice, with access to nominated discussants, and requesting more information from sponsors if required**	Draft ATAGI advice	Vaccine Evaluation Group, ATAGI discussants	***12 weeks to complete***
(2x)	[ATAGI teleconference meeting; other Agenda Items including post-submission advice from previous rounds.]			*[8-9 weeks, as per existing meeting schedule, 1 week post PBAC ESC]*
2a	*Draft ATAGI advice provided to discussants and sponsor.*		Vaccine Evaluation Group ATAGI discussants	***6 weeks before ATAGI meeting***
2b	*ATAGI discussants and sponsor provide feedback on draft advice to Vaccine Evaluation Group*	Feedback on draft ATAGI advice	ATAGI discussants, sponsors	***4 weeks before ATAGI meeting***
2c	*Vaccine Evaluation Group updates the draft advice based on feedback from discussants and sponsor; distributed to ATAGI in preparation for meeting*	Updated draft ATAGI advice	Vaccine Evaluation Group	***2 weeks before ATAGI meeting.***
3	**ATAGI face-to-face meeting: consider and determine ATAGI advice.** *Draft advice amended where necessary and ratified.*	ATAGI advice	ATAGI, ATAGI discussants Vaccine Evaluation Group	***Week 0***
3a	*Ratified ATAGI advice delivered to sponsor and PBAC*		ATAGI Secretariat	***2 weeks after ATAGI meeting***
(3x)	*PBAC submission lodged*		Sponsor	***9 weeks after ATAGI meeting***
3b	*PBAC request post-submission advice from ATAGI (matters arising from evaluators, ESC, PBAC and Department)*	Request for post-submission ATAGI advice	PBAC/ESC/Evaluators/Dept	
4	**ATAGI/secretariat provide post-submission advice to PBAC and sponsor**	Post-submission advice	ATAGI	***By PBAC meeting***

3 Confidentiality and transparency

The Australian Government, ATAGI and the PBAC and its subcommittees, are committed to being as open as possible in proceedings and providing as much information as possible in relation to listing vaccines on the NIP. The constraints on providing all information associated with submissions to the PBAC and other listing documents arise generally from considerations of privacy, commercial sensitivity and as a consequence of the operation of relevant Commonwealth Acts and Regulations.

A number of Acts made by parliament are relevant to the management and release of information, which form part of the procedures for listing a medicine/vaccine on the PBS/NIP. The information includes submission documents prepared by sponsors to list medicines/vaccines on the PBS/NIP, other general submissions to the PBAC, all agenda items considered by the PBAC, and other letters and applications made directly to the Australian Government Department of Health. Relevant Acts include:

- *National Health Act 1953*. This Act establishes the PBS. Section 135A of this Act specifically deals with the protection of information obtained for the purpose of the Act and provides for an offence for inappropriate disclosure
- *Health Insurance Act 1973*
- *Privacy Act 1988*. This Act regulates how personal information is handled, and includes Australian Privacy Principles with which all Australian Government agencies comply
- *Freedom of Information Act 1982*. This Act provides a legally enforceable right of access to government documents
- *Copyright Act 1968*
- *Archive Act 1983.*

Specific provisions dealing with the confidentiality of information are provided for in contracts between contractors for services and the government, and deeds of agreement between pharmaceutical companies and the government.

The Australian Government and the Government of the United States of America signed the Australia – United States Free Trade Agreement (AUSFTA) in 2004, which came into effect on 1 January 2005. There are agreed-to principles in relation to transparency and the processes that apply to both countries in managing their respective pharmaceutical programs at the federal level.

These principles are found in Annex 2-C – Pharmaceuticals of the AUSFTA. An explanation of these can be found on the Department of Health's website about the AUSFTA.

3.1 Managing and assessing confidential material

3.1.1 Material contained in submissions

Australian Government Department of Health

Electronic and paper-based records are maintained by the Australian Government Department of Health to show what happened, when and how it happened, who was involved, what was decided or recommended, what advice or instruction was given, and the order of decisions or events. The department maintains policies and procedures to ensure the management and storage of records is consistent, accurate and appropriate.

Submissions to the Australian Technical Advisory Group on Immunisation (ATAGI) are usually supplied in electronic format (refer to Section 5). The USB or a similar storage device that is supplied by sponsors is kept in a secure storage area in the Office of Health Protection, and access to the area is limited. Submissions that are emailed are stored in the Department of Health's IT system. General submissions and other correspondence are filed and stored in a secure area within the Immunisation Branch and electronic copies are made for the ATAGI agenda. The contents of all submissions are stored in the Department of Health IT system in the electronic format that was provided in the submission.

Access to the contents of the submission is limited to officers who need to work on the submission material. Access is controlled by senior officers in Immunisation Branch.

The contents of submissions are potentially subject to release under Freedom of Information legislation and may also be subject to requests of the Parliament.

Contractors evaluating submissions and working on agenda items for the ATAGI

The external evaluation entity (see Section 6.2) receives electronic copies of submissions that are allocated for them to evaluate. The conditions of storage, management and disposal of submission material are explicitly stated in the department's contracts.

Signed deeds of confidentiality are required by all people undertaking evaluations or other work for ATAGI. Employees and subcontractors of each external evaluation group agree not to disclose information provided in the submission to a 'third party' – that is, they will maintain confidentiality in regard to the content of submissions and other ATAGI materials.

Members of ATAGI

All agenda material is provided to committee members in electronic form.

Members of the ATAGI, are required to sign a deed of confidentiality when appointed. The deed includes text about not disclosing information provided in the agenda papers to a 'third party'.

Members are advised of the requirements to securely handle and dispose of confidential material appropriately, whether electronic or printed.

Other interested parties

From time to time, other parties will need to have information from submissions or ATAGI agenda papers released for specific purposes. These include – but are not limited to – giving technical or expert advice, assisting with implementation or providing a consumer perspective. Examples of the people who may have access to this material are other officers within the department, such as the Therapeutic Goods Administration (TGA) and Technology Assessment and Access Division (TAAD), and non-department employees such as clinicians or other health care professionals, and members of the Advisory Committee on Vaccines.

Where these other parties are not currently Australian Government employees, they will have access to submission material after they sign a Deed of Confidentiality that includes text about not disclosing any information provided in the agenda papers to a 'third party'. All attendees at meetings are required to dispose of any electronic and paper material appropriately.

3.1.2 Material contained in contracts and deeds

All material in contracts and deeds is managed according to the requirements set out in the contract or deed.

3.2 Managing conflicts of interest

Conflict of interest documents are managed under departmental procedures consistent with the *Privacy Act 1988*, and storage and handling of this personal information is protected. OHTA maintains a record of all conflicts of interest and the actions taken to address these by the relevant evaluation group, committee or other interested parties.

3.2.1 Management of conflict of interest by members of the ATAGI

The department takes appropriate steps to identify interests and manage potential conflicts of interest in relation to submissions to the ATAGI.

A *Disclosure of Potential Conflicts of Interest* (CoIs) form is completed by each member prior to their appointment on ATAGI. A selection panel consisting of the ATAGI Chair, consumer representative and department, determines if CoIs are suitable for membership.

Each member's declaration is classified into one of three categories which determines the level of decision making at ATAGI meetings. These include exclusion from discussions (A), participation but not final endorsement of decisions (B); or transparency (C).

The ATAGI members CoIs and their determinations are distributed to all members as part of the ATAGI meeting papers with members able to query determinations if required. A summary of ATAGI members CoIs are published in minutes of each meeting and available on the Department of Health website at Department of Health website - ATAGI.

All ATAGI members must confirm whether any additional conflicts have arisen before attending each meeting and at each meeting. A signed declaration is provided by all members for each meeting and stored by the Department.

3.2.2 Management of conflict of interest for Vaccine Evaluation Groups

Vaccine Evaluation Groups will be contracted under the Health Technology Assessment, Research Support and Other Support Services Panel, and as such will be subject to the rules and regulations, including those relating to conflict of interest, of that contract.

Evaluation entities inform the department of any relevant conflict of interest with submissions to be considered. Each group informs the department of any relevant conflicts of interest in relation to their allocated submissions.

Where there is an unavoidable conflict, the department makes arrangements to manage the identified conflict.

4 Key participants

This chapter outlines the key participants and their roles in the process of obtaining ATAGI advice.

4.1 ATAGI

ATAGI is a non-statutory committee with a key role in providing the PBAC and ESC with technical advice in relation to the consideration of listing a vaccine on the NIP. It should be noted that the provision of advice for vaccine listing is just one function of ATAGI. The terms of reference for ATAGI can be found at www.health.gov.au/resources/publications/atagi-terms-of-reference.

ATAGI membership is made up of specialists in various fields related to vaccination. This includes vaccinology, microbiology and immunology specialists, vaccine-preventable disease specialists, epidemiologists, general practitioners, vaccination providers and program coordinators, and consumers. To appoint members, an Expression of Interest process is undertaken by the Immunisation Branch of the Department of Health. Individuals are selected based on experience and skills required by the Committee, and are appointed to ATAGI by the Minister for Health.

Specialists in a particular field may also be co-opted onto ATAGI on an as-needs basis. This may occur when issues arising in relation to a particular vaccine require specialist advice outside of ATAGI's usual membership. When the need for extra expertise for a submission is identified by the Department, ATAGI Chair, ATAGI discussants (see 4.2) or the Vaccine Evaluation Group, the Department can invite an appropriate expert to join ATAGI for the duration of the request. Arrangements for co-opting members onto ATAGI for limited time periods are handled by the Department.

4.1.1 Role of ATAGI members in the advice process

ATAGI members are required to read the sponsor's *Request for ATAGI advice* and the draft advice developed by the Vaccine Evaluation Group prior to the meeting at which it will be considered. During the meeting, members will contribute to discussion so that a consensus position on the advice can be reached. They will be expected to apply their specialist technical, clinical and programmatic expertise to the issues that arise within the *Request*. Once agreement has been reached, ATAGI endorse the advice pending any changes required.

4.2. ATAGI discussants

The ATAGI Chair and the Department will together appoint two discussants for each *Request for ATAGI advice*, based on expertise and availability. One discussant should have vaccinology expertise, and one should have clinical and/or vaccine program management expertise. Conflict of interest will have been declared before membership to ATAGI was granted, however it may be appropriate for nominated discussants to re-declare any conflicts of interest once the vaccine that is the subject of the *Request* is known.

4.2.1 Role of ATAGI discussants

The role of the discussants is to lead the conversation about the advice at the ATAGI meeting, targeting the areas of most uncertainty, where discord may be likely, or where specific technical advice is required. To this end, discussants will work with the external Vaccine Evaluation Group to develop the draft advice and will liaise with them on any relevant matters prior to ATAGI meeting. However, it is intended that the discussants provide guidance and expert input to the Vaccine Evaluation Group, but

do not produce the advice themselves. In this way, the time and expertise of the discussants, and the entire ATAGI committee, is most efficiently used.

The ATAGI advice will follow a standard template that will facilitate the identification of key issues by the discussants (and ATAGI in general). With the advice more synthesised and key issues for consideration already identified by the Vaccine Evaluation Group, time will be more efficiently spent by discussants.

Depending on need, discussants may be involved in a teleconference between the Vaccine Evaluation Group and the Department whilst the draft advice is being prepared. Through the channel of the Department, discussants can also seek written clarifications or additional information from sponsors, as required.

Following the ATAGI meeting, the discussants ensure that any changes and ATAGI decisions are properly incorporated into the draft advice. Depending on the extent of any changes, the discussants may also be called upon to provide final endorsement of the advice, along with the ATAGI Chair.

4.3 Department of Health – ATAGI secretariat

The **Immunisation Policy Section (IPS)** is part of the **Immunisation Branch (IB)** of the Office of Health Protection, within the Australian Government Department of Health. The IB are responsible for the implementation and management of immunisation programs and policies to support them, including procurement of vaccines for the NIP, providing evidence-based technical and policy advice to support the NIP, liaising with the Technology Assessment and Access Division on PBAC consideration of vaccines for the NIP and providing secretariat support for ATAGI, and Jurisdictional Immunisation Coordinators. (9)

4.3.1 Role of the Department of Health (ATAGI secretariat)

The ATAGI secretariat, along with the ATAGI Chair, review the *Request for ATAGI advice* to ensure that the Guidelines are met and all necessary documentation is included, and in consultation with the ATAGI chair, determine whether the *Request* is simple or complex. The timeline for advice is not affected by the classification of simple or complex, however the costs are different. The final decision about whether a *Request* is simple or complex lies with the Department.

The Department then allocate the *Request* to an external Vaccine Evaluation Group, and provide them with the relevant papers. Additionally, the Department will liaise with the ATAGI Chair to allocate the *Request* to two ATAGI discussants, based on expertise and availability.

Where it is required, the Department will facilitate correspondence between the Vaccine Evaluation Group, discussants and the sponsor.

In consultation with ATAGI discussants and Chair, the Department will ensure that the final ATAGI advice has incorporated all the required changes, and is endorsed by ATAGI, before delivering it to the sponsor and the PBAC secretariat.

The Department can also provide policy papers to PBAC, where the Department feels policy issues should be considered as part of the PBAC process.

4.4 Vaccine Evaluation Group

A panel of expert Vaccine Evaluation Groups will be established by the department, through the Health Technology Assessment, Research Support and Other Support Services Panel. The Vaccine Evaluation Groups will need to demonstrate expertise in vaccines, vaccine-related diseases, evaluation methodology, the NIP and implementing vaccines onto the NIP. Requests for ATAGI advice will be allocated to groups based on experience and availability. Contract arrangements will be handled by the Department.

4.4.1 Role of Vaccine Evaluation Group

Before beginning the draft advice, the group will be required to review the *Request* and declare any conflicts of interest to the Department. Depending on the relevant departmental policy, conflicts of interest may preclude a group from undertaking the work; however this will be addressed on a case-by-case basis.

The Vaccine Evaluation Group will consider the *Request*, confirming the aspects of the PICO and clinical algorithm that are appropriate, noting where it is not appropriate, answering sponsor questions, and highlighting areas of uncertainty for ATAGI. The focus will be on the aspects of the *Request* that will impact on the sponsor's PBAC submission. Such issues will include the appropriateness of the intended population, relevant comparators, specific and relevant outcomes, and the applicability of evidence to the intended use in Australia. Sponsors will also be able to ask specific questions of ATAGI which will be addressed by the Vaccine Evaluation Group and ATAGI as required.

Draft advice will follow a template. The purpose of the template is to provide the necessary advice in a synthesised, systematic way, so that it is easier and more efficient for ATAGI to provide comment, for the sponsor to integrate into their assessment and for PBAC (the committee, evaluators and ESC) to utilise. The template will also allow space for the Vaccine Evaluation Groups and ATAGI to share other relevant information with the sponsor and PBAC.

5. Procedure for obtaining ATAGI advice

Following is an explanation for each stage of the process for obtaining ATAGI advice for a submission to PBAC, as described in Figure 1.

Preliminary meeting

Timeline: meetings available on an as-needs basis, or as set by the Department

Sponsors will have an opportunity to meet with representatives of the Immunisation Branch of the Department to discuss their future proposal for a vaccine submission. This will enable both sponsor and Department to decide if the proposed vaccine, indication and position on the NIP is suitable for the NIP. This will help sponsors avoid proceeding with an application that is unlikely to be supported by ATAGI due to irrelevance (such as a lack of clinical need). However it should be noted that the process only informs the sponsor if their proposed vaccine is suitable for the NIP. This process does not provide sponsors with ATAGI advice on the matters specific to their submission; these issues must be addressed through the formal *Request for ATAGI advice* process. Likewise, a positive outcome from the meeting does not infer that the submission will be supported by ATAGI; only that the proposal is likely to be relevant to the Australian clinical setting. A preliminary meeting is not compulsory, and only one meeting per potential submission can be accommodated. The meeting outcome does not preclude addressing all the evidence requirements in the *Request for ATAGI advice* guideline.

Pre-process: intention to submit

Timeline: at least 22 weeks before ATAGI meeting

Sponsors are required to inform the ATAGI secretariat of their intention to submit a *Request for ATAGI advice*, at least two weeks before the *Request* is due. This will allow the department to begin arrangements for allocation to a Vaccine Evaluation Group (VEG) and to the ATAGI discussants. The intention to submit should include the vaccine and the proposed listing, including any restrictions to the intended population, so that appropriate expertise can be allocated.

Stage 1: Sponsor *Request for ATAGI advice* submitted to Department

Timeline: 20 weeks before ATAGI meeting

Sponsors complete their *Request for ATAGI advice* and deliver it via email to the ATAGI secretariat within the Department of Health.

The *Request* should follow the *Guidelines for preparing a request for advice from the Australian Technical Advisory Group on Immunisation (ATAGI) to support Pharmaceutical Benefits Advisory Committee (PBAC) consideration of vaccines*. The information contained in the *Request* is designed to provide ATAGI with all the relevant contextual information about the intended PBAC submission.

As the text can be easily integrated into the PBAC submission format, workload duplication is minimised. Sponsors also need to nominate whether their *Request* is simple or complex, with justification.

The *Request* should be delivered to the ATAGI secretariat within the Department by the due date (given on the website and aligned to ATAGI and PBAC meeting dates).

Each *Request* will be checked for completeness and returned to the sponsor if incomplete. Requests not completed by the time it needs to be provided to the Vaccine Evaluation Group (18 weeks before ATAGI meeting) will not be considered in that cycle.

Stage 1a: Department handles contractual arrangements for production of draft ATAGI advice

Timeline: 18 weeks before ATAGI meeting (within two weeks of receiving Request)

The Department, in consultation with the ATAGI Chair, review the *Request* to ensure that all relevant sections are complete and that all documentation is included. They will also determine if the *Request* is simple or complex, and allocate the *Request* to an external Vaccine Evaluation Group, according to expertise and availability. The Department, in consultation with the ATAGI chair, will also allocate the ATAGI discussants, also based on expertise and availability.

Stage 2: Vaccine Evaluation Group prepares draft ATAGI advice

Timeline: group has 12 weeks to prepare draft advice (deadline six weeks before ATAGI meeting)

Using the sponsor's *Request*, and the ATAGI advice template, the nominated Vaccine Evaluation Group will prepare the draft advice. The advice will confirm or challenge the PICO criteria set out by the sponsor, and will provide technical advice on aspects of the PICO as required. The advice will also address the implementation issues proposed by the sponsor, and suggest any other issues not identified. The draft advice will also present the key issues requiring discussion and decision at the ATAGI meeting.

There will be the opportunity for a teleconference between the Vaccine Evaluation Group, ATAGI discussants and the Department whilst the draft advice is being prepared. Additional written information may be sought from the sponsor, if required.

Stage 2a: Draft ATAGI advice provided to ATAGI discussants and sponsor

Timeline: Six weeks before ATAGI meeting

The draft advice will be provided to the ATAGI discussants and the sponsor, for comment before the ATAGI meeting.

Stage 2b: ATAGI discussants and sponsors provide feedback on draft advice to the Vaccine Evaluation Group

Timeline: Four weeks before ATAGI meeting (2 weeks after receiving draft advice)

The ATAGI discussants will review the draft advice and the sponsor's *Request* and provide feedback to the Vaccine Evaluation Group where necessary. This ensures that the draft advice is in its most developed form and that any issues that require further input can be attended to before the ATAGI meeting.

Sponsors must respond to the draft in writing, no more than two pages, to the ATAGI secretariat, within the specified time frame.

Stage 2c: Vaccine Evaluation Group updates draft advice

Timeline: Draft advice complete 2 weeks before ATAGI meeting

Based on feedback from and consultation with the discussants, and the sponsor's response, the Vaccine Evaluation Group amends the draft advice, where appropriate, in preparation for the ATAGI meeting.

Stage 3: ATAGI meeting to consider and ratify ATAGI advice

Timeline: ATAGI meeting

The discussants lead the discussion of the draft advice at the ATAGI meeting, highlighting the issues requiring decisions by the committee and addressing any specific questions from the sponsors.

Decisions made by ATAGI and required amendments to the draft advice are made by the Vaccine Evaluation Group and/or the ATAGI secretariat. ATAGI will need to decide if the changes are small enough that the advice can be ratified without further scrutiny, or if the proposed changes will need to be checked by the discussants and/or the ATAGI chair, out of session.

3a: Ratified ATAGI advice delivered to sponsor and PBAC

Timeline: 2 weeks following ATAGI meeting

The ATAGI secretariat within the Department has the responsibility of ensuring the ratified ATAGI advice is delivered to the sponsor and to the PBAC secretariat within two weeks of the ATAGI meeting. This will give ample time for the sponsor to incorporate ATAGI's technical advice into their submission to PBAC.

3b: PBAC (evaluators, ESC or PBAC) request post-submission advice from ATAGI

Timeline: TBA

PBAC, the evaluators, or ESC may require further information from ATAGI once they have considered the complete PBAC submission (prior to the PBAC meeting). The template for requesting post-submission advice should be used. ATAGI members will not have seen the PBAC submission and will therefore be unfamiliar with where the submission may have deviated from their advice. Thus it is important for the post-submission advice request to describe the context and provide relevant information from the submission and pre-submission advice. This will enable ATAGI to answer the specific questions with the most accuracy and succinctness.

Stage 4: ATAGI provide post-submission advice; Department provide policy papers

Timeline: by PBAC meeting

Once the sponsor has lodged the submission with PBAC (following the PBAC Guidelines), the PBAC evaluators, ESC, PBAC or the Department may have further questions for ATAGI. These questions will follow a template, ensuring that the context for the required information is well understood by ATAGI and can be answered as clearly. The request for ATAGI post-submission advice will be directed through the ATAGI secretariat and in the first instance, the discussants will have responsibility for responding to the queries with support from the Vaccine Evaluation Group. However, committee input can also be obtained at the ATAGI teleconference meeting (1 week post ESC meeting). Post-submission advice is then returned to the PBAC secretariat so that it can be delivered to the sponsor at the same time as the ESC advice. This enables the sponsor to consider the two documents simultaneously.

At this stage, the Department also have the opportunity to provide relevant policy information to PBAC that they wish to be considered along with the ATAGI advice, for example comments on implementation or program issues.