



Australian Government

**Department of Health
and Aged Care**

ATAGI decision- making process for developing clinical recommendations in the **Australian Immunisation Handbook**

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Acronyms and abbreviations

Term	Definition
ATAGI	Australian Technical Advisory Group on Immunisation
GRADE	Grading of Recommendations, Assessment, Development and Evaluation
Handbook	Australian Immunisation Handbook
NCIRS	National Centre for Immunisation Research and Surveillance
NHMRC	National Health and Medical Research Council
NIP	National Immunisation Program
PBAC	Pharmaceutical Benefits Advisory Committee
PICO	population, intervention, comparator, outcomes
Portfolio Lead	ATAGI members assigned to lead disease/topic areas. An individual ATAGI Portfolio Lead may not necessarily be the lead member responsible for every piece of advice related to that particular topic.
TGA	Therapeutic Goods Administration

Introduction

The [Australian Technical Advisory Group on Immunisation \(ATAGI\)](#) provides evidence-based advice and clinical recommendations on the use of vaccines in Australia.

ATAGI's recommendations are based on a rigorous process of reviewing scientific evidence and data, considering potential implementation issues, and incorporating societal values about the use of vaccines in the Australian context. These recommendations are then implemented by healthcare providers across Australia to protect people who are at risk of vaccine-preventable diseases and help ensure the safe, effective and equitable use of vaccines.

This document describes the steps in ATAGI's current decision-making process that lead to the clinical recommendations in the [Australian Immunisation Handbook \(the Handbook\)](#).

About ATAGI

ATAGI's vision is to protect the Australian population from vaccine-preventable diseases.

ATAGI's role is to:

- advise the Minister for Health on the medical administration of vaccines available in Australia, including those available through the [National Immunisation Program \(NIP\)](#)
- advise the [Pharmaceutical Benefits Advisory Committee \(PBAC\)](#) on vaccine effectiveness and use in Australia
- through the Australian Government Department of Health and Aged Care, provide advice to research organisations on current immunisation research and areas that need more research
- consult with relevant organisations to produce the Handbook
- consult with relevant organisations in implementing immunisation policies, procedures and vaccine safety.

[ATAGI's membership](#) includes technical experts, immunisation nurses, general practitioners and a consumer representative.

ATAGI assigns one or more members as Portfolio Leads for each vaccine-preventable disease and Handbook chapter. The Portfolio Leads are the key content experts steering the work relating to that disease or chapter. They may also act as discussants to lead ATAGI's consideration of any PBAC submissions relating to that disease, and provide subject matter expertise for Handbook chapter updates.

ATAGI has 6 formal meetings every year, of 1 to 2 days each.

Australian Immunisation Handbook

ATAGI develops recommendations for the use of vaccines in Australia and oversees the content of the Handbook. The Handbook provides clinical guidelines for healthcare professionals and others about using vaccines safely and effectively. It includes a chapter for each vaccine-preventable disease that is relevant in the Australian context, as well as information about vaccination procedures, vaccination schedules and groups with special vaccination requirements.

The Handbook is endorsed by the National Health and Medical Research Council (NHMRC). The Handbook follows [NHMRC processes for guideline development](#) by:

- using a multidisciplinary committee
- taking a rigorous approach to reviewing the evidence and making recommendations, including the use of Grading of Recommendations, Assessment, Development and Evaluation (GRADE)
- ensuring transparent development and decision-making processes
- being informed by expert judgement, as well as by the views of consumers, community groups and other people affected by the guidelines
- having robust processes in place to manage conflicts of interest.

In approving the Handbook recommendations, NHMRC is satisfied that the recommendations are systematically derived, based on the identification and synthesis of the best available scientific evidence, and developed for health professionals practising in an Australian healthcare setting.

PBAC advice

The PBAC is an independent expert body appointed by the Australian Government. Its main role is to recommend new medicines for listing on the Pharmaceutical Benefits Scheme (PBS), including listing new vaccines on the NIP. The PBAC considers comparative clinical effectiveness, safety and cost-effectiveness when making its recommendations.

Vaccine sponsors prepare submissions to the PBAC to have their vaccine considered for listing on the NIP. Sponsors must seek advice from ATAGI before making their submission to the PBAC. ATAGI provides advice to the PBAC and the sponsor on the submission, and also provides any additional advice requested by the PBAC to help it make a recommendation.

The Department of Health and Aged Care contracts vaccine evaluation groups to provide technical expertise and develop ATAGI advice on PBAC submissions, in collaboration with ATAGI Portfolio Leads. This advice is discussed and endorsed by ATAGI before being provided to the PBAC and the sponsor.

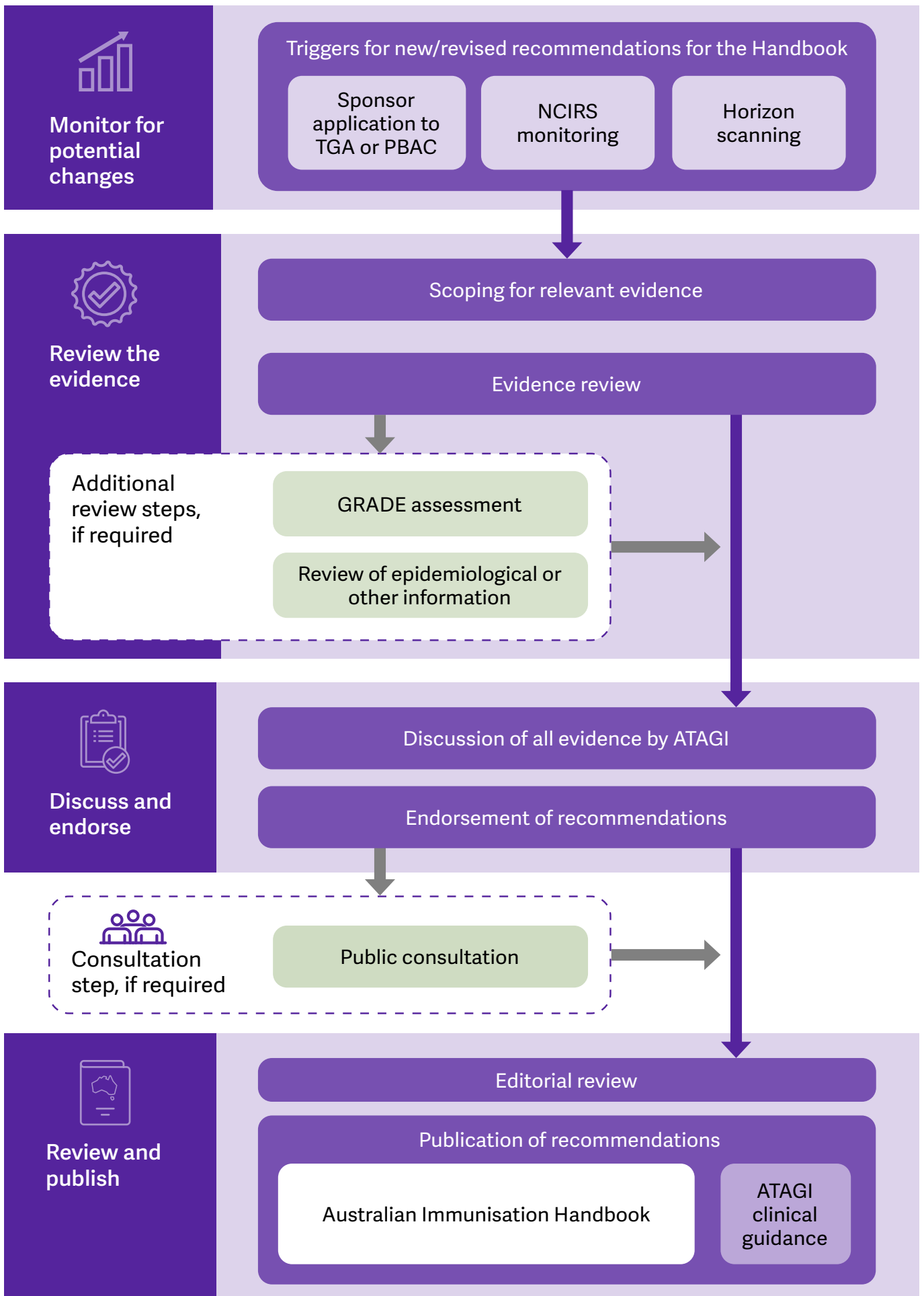
ATAGI's procedures and decision-making process for providing advice to the PBAC are separate from the process for making recommendations about the clinical use of vaccines in the Handbook. More details on the PBAC process are in the [ATAGI guidelines, procedures and templates](#).

ATAGI support

Scientific technical support to ATAGI is provided by the National Centre for Immunisation Research and Surveillance (NCIRS).

Secretariat support to ATAGI is provided by the Department of Health and Aged Care. The Department also engages technical communication specialists to assist with writing and editing some ATAGI communications, including the Handbook.

Developing clinical recommendations for the Handbook





Monitor for potential changes

The need for a new or revised recommendation is triggered by a change in the immunisation landscape. This may include:

- a sponsor applying to the Therapeutic Goods Administration (TGA) or the PBAC
- NCIRS monitoring scientific literature, other information sources and feedback from immunisation providers
- ATAGI horizon scanning for potential changes to the vaccine development landscape.

Sponsor application to the TGA or the PBAC

ATAGI is notified through the Department of upcoming vaccine submissions to the TGA or the PBAC. Examples of these submissions include:

- a new vaccine or formulation
- a new indication or population group who could receive a vaccine
- a revised schedule for a vaccine course.

ATAGI members discuss the implications that this proposed change might have for the current recommendations in the Handbook.

NCIRS monitoring

As the expert national centre on immunisation, NCIRS continually monitors the immunisation landscape, including:

- epidemiology of vaccine-preventable diseases, including breakthrough cases of disease in vaccinated people
- evaluations of vaccination programs
- clinical issues with vaccine use in Australia, including signals from vaccine safety surveillance
- feedback on the Handbook from providers and expert advisory groups.

NCIRS maintains a tracking list of issues from these sources. If any issues may warrant new or revised Handbook recommendations, NCIRS proposes this to ATAGI for discussion.

Horizon scanning

ATAGI uses horizon scanning to monitor potential changes to the vaccine development landscape in the near future. This includes monitoring the submissions, discussions and recommendations from international regulators and national immunisation technical advisory groups of other countries. Issues that these groups consider may also be relevant for Australia, and vaccine sponsors may make submissions to these groups in other countries before they make submissions in Australia.

Horizon scanning also involves active communication with key stakeholders. At each meeting, ATAGI receives a report from the Communicable Diseases Network Australia (CDNA), which is a subcommittee of the Australian Health Protection Principal Committee (AHPPC). ATAGI may also invite experts to present at a meeting. ATAGI holds an Industry Day each year, at which vaccine sponsors are invited to present information on vaccines in their pipeline and respond to ATAGI questions.

ATAGI members consider any issues raised by horizon scanning in the context of the current recommendations in the Handbook.



Review the evidence

If monitoring activities trigger a potential change to the Handbook recommendations – or to specific guidance on practice points under a recommendation – NCIRS works with the Portfolio Leads to review the evidence. This includes scoping for evidence relevant to the issue, followed by a detailed targeted review of evidence. A GRADE assessment and/or review of epidemiological and other relevant information is included in the evidence review process for a recommendation change, or for some practice point changes, if required.

Scoping for relevant evidence

NCIRS searches for relevant evidence and sources to clarify the volume and types of studies contributing to available evidence for an issue, and assesses the need for a Handbook update and the potential extent of Handbook changes. Scoping and information-gathering activities may include:

- approaching sponsors or other investigators for additional unpublished information, and to confirm any plans and timelines for a TGA submission, a PBAC submission and/or supply of the vaccine in Australia

- identifying populations that are potentially relevant for the issue
- reviewing the approaches, policies and recommendations of other countries on the use of the same or similar vaccine(s)
- identifying relevant completed studies (published or unpublished) and studies in progress
- considering other interventions relevant to control and prevention of the disease.

ATAGI discusses the findings from these scoping activities at a meeting. In some cases, ATAGI might decide after the scoping process that no change to the Handbook is warranted.

Evidence review

If the scoping activities indicate that new evidence is available to inform a change to the Handbook, NCIRS conducts a more detailed evidence review. Depending on the nature of the potential change, the evidence review may include:

- published studies, including clinical studies, laboratory studies, and analyses of safety and effectiveness
- unpublished or preprint data, if available
- data on vaccination coverage or epidemiology
- program evaluations
- additional tailored analysis (by NCIRS) of primary data that target specific policy-relevant questions.

The nature and extent of the evidence review will vary depending on the type of Handbook change required.

GRADE assessment of evidence on the use of a vaccine (when applicable)

Since July 2020, ATAGI has used Grading of Recommendations, Assessment, Development and Evaluation (GRADE) for developing new or revised Handbook recommendations. This aligns with the NHMRC process for developing clinical guidelines in Australia.

GRADE is a framework for rating the quality of the available evidence about a healthcare intervention in a systematic review, and developing

and grading the strength of healthcare recommendations in guidelines. It involves a structured expert consensus approach and process to support decision-making that is evidence based, standardised and transparent.

Applying GRADE when developing clinical guidelines is recommended by international guideline development bodies such as the World Health Organization (WHO). The WHO Strategic Advisory Group of Experts (SAGE) on Immunization and the Advisory Committee on Immunization Practices (ACIP) in the United States have used GRADE for developing some of their recommendations on use of vaccines.

In the ATAGI decision-making process, GRADE assessment is applied if there is enough evidence to compare 2 (or more) interventions (often a new vs a currently recommended vaccine or schedule) in a particular age group or population group. GRADE reports on specified outcomes that are deemed critical or important for a new or changed recommendation for use of a particular vaccine. GRADE may also be applied to inform decisions on guidance or practice points within a recommendation.

Throughout the GRADE process, NCIRS works closely with Portfolio Leads (and other ATAGI members, if required) to:

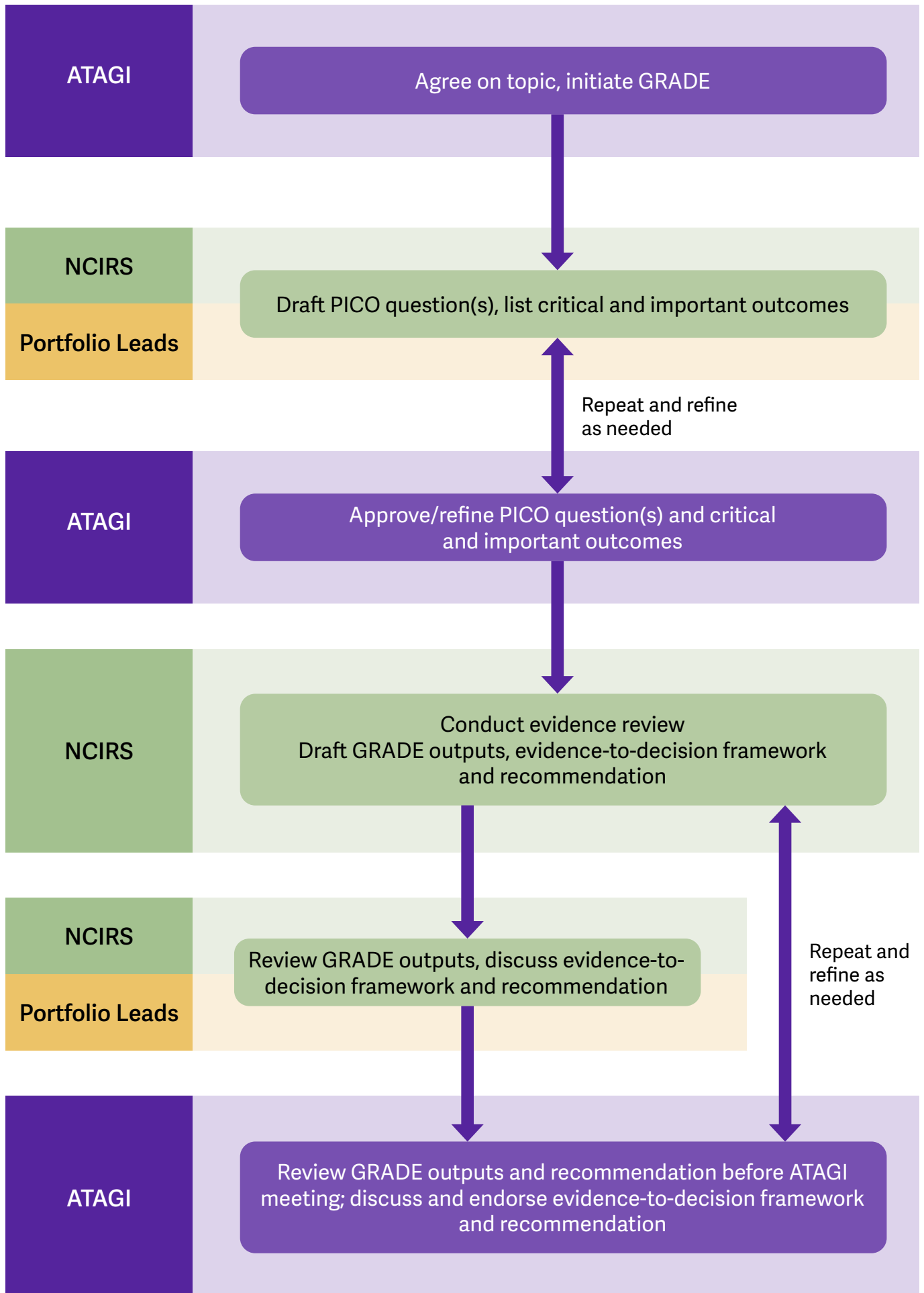
- draft and refine the research questions and PICO (population, intervention, comparator, outcomes) questions
- identify the relevant outcomes for assessment
- conduct the required systematic literature reviews
- develop the GRADE outputs.

The full ATAGI committee reviews and discusses the draft PICO questions, and determines the ranking of the critical and important outcomes, before the evidence review is conducted. The full ATAGI committee also reviews and discusses the GRADE outputs – including the summary of findings, evidence-to-decision tables and recommendations – at an ATAGI meeting. If necessary, the GRADE outputs and recommendations are revised to address any issues raised, before the final outputs are endorsed by ATAGI.

Expert methodological consultancy support is provided to NCIRS by the [Melbourne GRADE Centre](#), if needed.

The GRADE evidence-to-decision process also allows for consideration of issues other than safety and effectiveness that might influence the recommendation. These issues are explored in a separate review of epidemiological and other information, if needed.

GRADE assessment process



Review of epidemiological and other information (if required)

Some potential changes to recommendations involve aspects other than the safety and effectiveness of a vaccine that are important to consider when formulating the recommendation for its use. Examples include:

- disease burden in specific population groups in Australia – for example, age groups, Aboriginal and Torres Strait Islander peoples, geographical regions, populations at higher risk of disease
- ethics and equity
- alignment with the current program
- vaccine supply issues
- implementation issues.

In these cases, other data will be reviewed to inform the recommendation. This may include data on disease notifications, vaccine coverage, or vaccine acceptability or confidence.

Review of these aspects is separate and additional to the GRADE assessment, which focuses on an intervention (vaccine) and a comparator for specified population(s).



Discuss and endorse

When the relevant evidence has been reviewed, the outputs are discussed and revised with the Portfolio Leads and then the full ATAGI committee, if needed, until ATAGI finalises and endorses the changes to the recommendations.



Public consultation (if required)

If the decision is to change a recommendation or add a new recommendation to the Handbook, the NHMRC process requires a 30-day public consultation period. This provides an opportunity for input from consumers and stakeholder organisations on the proposed changes. This public consultation process is additional to any targeted consultation with various expert committees or specialty groups that ATAGI may undertake.

NCIRS works with technical communication specialists to draft a public consultation document, which outlines the proposed recommendation changes, rationale and supporting evidence. This is endorsed by the full ATAGI committee before being published on the [Department of Health and Aged Care Consultation Hub](#). The Department communicates with peak bodies and key stakeholder groups to inform them that consultation is open

and invite them to make a submission. A link to the Consultation Hub is also added to the Handbook home page.

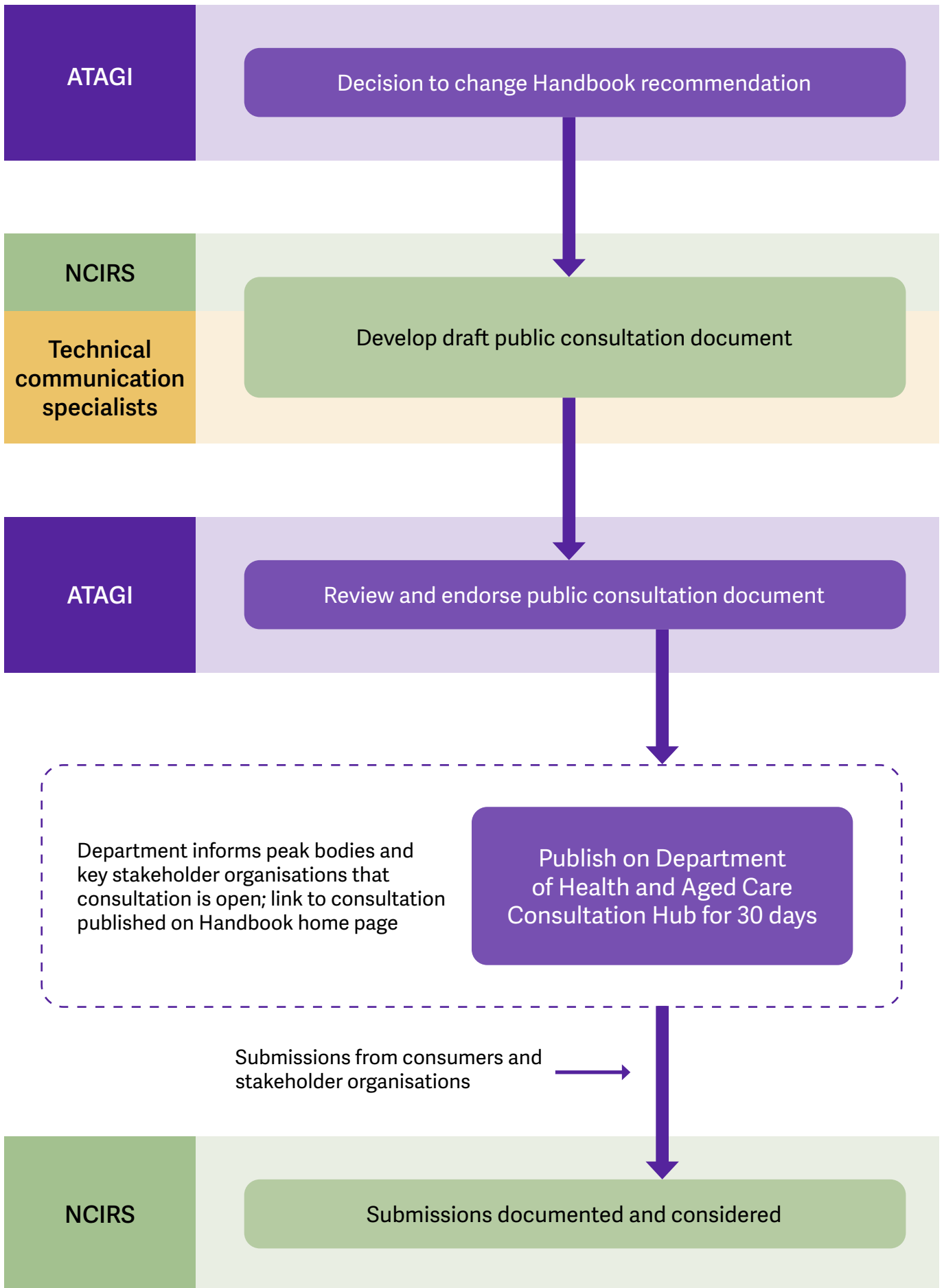
After the 30-day consultation period, all submissions are documented and considered, and any further changes to the recommendations are discussed and endorsed by ATAGI.

NCIRS works with technical communication specialists to update the Handbook chapter to incorporate the changes to recommendations. Both the draft chapter and a summary of the submissions from public consultation are provided to NHMRC for endorsement.

Public consultation is not required if the proposed changes involve practice points within a recommendation, rather than the recommendation itself. However, ATAGI may choose to undertake public consultation for changes to practice points. Examples of situations in which public consultation is not required (but may be undertaken at ATAGI's discretion) include:

- the addition of an equivalent alternative brand of a vaccine as an option to be used according to existing recommendations
- a change in the optimal timing of administration of doses for an existing vaccine
- clinical guidance on managing deviation from standard clinical practice or managing administration errors.

Public consultation process





Review and publish

After final endorsement of changes by ATAGI (and by NHMRC if required), the updated Handbook chapter undergoes final editorial review to ensure consistency and readability. The final Handbook chapter is approved by the Chief Medical Officer and updated online.

ATAGI also occasionally publishes ATAGI statements or clinical advice, such as the annual ATAGI statement on seasonal influenza or information on NIP changes. This usually occurs if the information or recommendations need to be published rapidly, or if immunisation providers would benefit from additional guidance to manage complex changes to the NIP.

If a GRADE assessment was completed, the final GRADE tables are published online at the same time as the chapter update.

The Department of Health and Aged Care communicates about Handbook changes and ATAGI advice through several channels, to ensure that immunisation providers and other healthcare professionals are aware of the changes to their clinical practice.