



Australian Government

**Department of Health
and Aged Care**

**ATAGI requests for pre-submission advice –
information for applicants**

Version 5, September 2023

Terms and acronyms

In this document:

- **we** refers to the Immunisation Branch of the Australian Government Department of Health and Aged Care
- **you** refers to the applicant requesting ATAGI pre-submission advice

ATAGI: Australian Technical Advisory Group on Immunisation

PBAC: Pharmaceutical Benefits Advisory Committee

HPP: Health Products Portal

Calendar

As of 1 July 2020, there are three cycles per calendar year for applicants to request pre-submission advice from ATAGI for a vaccine submission to the PBAC. Lodge your Notice of Intent and request dossier according to the timeframes below.

Step	December 2023 Meeting Cycle	April 2024 Meeting Cycle	August 2024 Meeting Cycle	December 2024 Meeting Cycle
Applicant notifies Department of intention to submit by lodging an 'Notice of Intent' request for ATAGI advice through the HPP	6 July 2023	16 November 2023	14 March 2024	4 July 2024
Applicant submits request for ATAGI advice to the Department (ATAGI Secretariat)	20 July 2023	30 November 2023	28 March 2024	18 July 2024
Applicant and discussants receive draft (6 weeks before ATAGI meeting)	26 October 2023	7 March 2024	4 July 2024	24 October 2024
Applicant comments due back to Department (2 weeks consultation)	9 November 2023	21 March 2024	18 July 2024	7 November 2024
ATAGI Meeting	7-8 December 2023	18 April 2024	15-16 August 2024	5-6 December 2024
Applicant receives final endorsed advice (2 weeks after ATAGI meeting)	21 December 2023	2 May 2024	29 August 2024	19 December 2024
Deadline for major submissions to PBAC	13 March 2024	Early July 2024**	Early November 2024**	Early March 2025**

**Dates to be finalised

How to lodge a request

Compile your dossier to support your request for advice according to the [published guidelines](#).

From 1 January 2023, the Health Products Portal (HPP) is the approved method for lodging requests for an:

- ATAGI pre-submission meeting
- ATAGI 'Notice of Intent'

For instructions on how to get started, please visit the [HPP website](#).

Please note that we are implementing functionality to allow the request for ATAGI advice dossier to be submitted through the HPP, which we expect will become available in early 2024.

Therefore, the HPP cannot yet be used for submitting the dossier of requests for ATAGI advice submission. In the meantime, the dossier can be submitted via ATAGI industry portal SharePoint site. Request for accessing the industry portal should be made via email to the [ATAGI Secretariat](#).

Fees 2023-2024 financial year

For the 2023-2024 financial year, the following fees apply to requests for ATAGI advice:

- Notice of Intent \$430
- Complex \$212,790
- Simple: \$117,390

The fees for Notice of Intent are included in the total cost of all complex and simple requests for ATAGI advice. The fees for complex and simple requests for ATAGI advice are published in the 2023-2024 Cost Recovery Implementation Statement on the [PBS website](#).

We will process all requests as 'complex' unless you have our agreement in writing that your application will be managed as 'simple'. We may grant partial exemption of fees for 'simple' ATAGI advice, but you must seek this exemption in writing.

If you wish to request 'simple' advice, please seek a meeting with the ATAGI secretariat before lodging your Notice of Intent to discuss whether your proposal meets the ATAGI guidelines criteria for a simple request.

Meeting prior to lodging a request

Before making a request for ATAGI advice, you are welcome to meet with us to seek feedback on submission plans. These meetings are not part of the cost recovery process and will cover only those parts of the process addressed by the ATAGI Guidelines. We may recommend that other Departmental representatives attend (for example from the Office of the Chief Medical Officer, the Immunisation Procurement team or the PBAC Secretariat).

We consider these meetings essential if you are seeking a 'simple' fee exemption. We also recommend a meeting if you are considering making a request for National Notifiable Diseases Surveillance System data to support epidemiological disease estimates. We suggest requesting a meeting date no closer than one month before the Notice of Intent cut-off for the targeted meeting cycle.

Bookings are now open for pre-submission meetings for the April 2024 ATAGI meeting cycle. Pre-submission meetings run for one hour and can be booked through the HPP for the following dates:

- Thursday 28 September 3:00 PM to 4:00 PM
- Thursday 5 October 3:00 PM to 4:00 PM

To request alternative meeting dates or for any other inquiries relating to ATAGI pre-submission advice please contact the [ATAGI Secretariat](#).

Managing timing

Please consider timing when making a request for ATAGI advice. The dates for lodging a request for ATAGI advice are fixed. The streamlined process does not allow for rolling data submission (i.e. it is not possible for applicants to submit additional data after the evaluation process has started, unless requested by ATAGI as part of the evaluation process).