Template for obtaining ATAGI advice, post-PBAC submission

A guide for PBAC evaluators, ESC and PBAC members

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Purpose

This document is designed to guide the process of obtaining post-PBAC (Pharmaceutical Benefits Advisory Committee) submission advice from ATAGI.

During evaluation of PBAC submissions, questions for ATAGI may arise from evaluators and members of the Economic Sub-committee (ESC) or PBAC. Because of their technical expertise, ATAGI are uniquely placed to answer questions that require specialist knowledge and experience, and this can help PBAC make decisions about vaccines to go on the National Immunisation Program (NIP).

To improve the efficiency and quality of post-submission advice, this template has been created to ensure that all the required information, particularly around context, is available to ATAGI in developing their post-submission advice. It is designed to be used by PBAC evaluators, and members of ESC or PBAC, who have questions for ATAGI on submissions they are considering.

The new ATAGI process requires sponsors to provide a request to ATAGI for advice that is structured around the PICO criteria (Population, Intervention, Comparator, Outcomes), clinical algorithm and predicted implementation of the vaccine onto the NIP. The process also requires that ATAGI advice to the sponsor and PBAC follows a template, which is intended to provide a synthesis of relevant evidence and to highlight areas of uncertainty. These measures are designed to make ATAGI advice more digestible and easier to use for both the sponsor and PBAC.

However, it is recognised that post-submission questions to ATAGI are likely to be highly specific to the vaccine under question, and submissions will not require post-submission ATAGI advice on the same issues. As such, the required information for requesting post-submission advice from ATAGI is described in general terms in this template, with examples provided so that requestors can ensure they provide all the information required by ATAGI to formulate the advice.

Vaccine name (brand):	
ATAGI unique identifier:	
Proposed listing indication:	

For each question of ATAGI, please complete the following:

1) Relevant section of PBAC submission (and corresponding section of ATAGI pre-submission advice if relevant)

2) Describe the area of uncertainty/disagreement. Provide details around why there is uncertainty.

(for example, the sponsor has used a different outcome measure metric to what was specified in the ATAGI pre-submission advice, and the evaluators/ESC/PBAC are unsure if the two measures can be considered equivalent).

Examples – uncertainty remains around the following issues:

Population issues

- is the choice of target population X appropriate given XYZ
- is the size of target population X in Australia underestimated due to ABC

Intervention issues

- whether the most effective dose is A or B cfu/mL
- whether the proposed dosing should include a booster at X months for Y high risk group

Comparator issues

- whether the choice of comparator for target population X should be A or B
- whether standard medical management includes intervention B

Clinical outcomes and assumptions for modelling

- whether assay results Z and X are interchangeable
- whether the duration of protection is lower/XYZ years in high risk group ABC

- whether the sponsor's assumption that immunogenicity of serogroup A can be extrapolated to serogroups B, C and D

Estimates of use

- whether uptake of vaccine in target population X will be lower/higher due to factors ABC
- what is the expected coverage/uptake in population X if the dosing intervals for the primary immunisation series are set at xx months apart (course to be completed within a year)? How does this expect immunogenicity?

3) Describe the exact advice you wish ATAGI to provide

(for example, do you want ATAGI to confirm that deviations from the pre-submission advice are acceptable or not? Do you want ATAGI to interpret evidence not considered in the pre-submission advice?)

Describe the uncertainty in clear terms, for example: 'Either the assay/correlate/value means A or it means B – depending on which is more likely/correct this will have ABC or XYZ implications for the cost-effectiveness in population XXX'.