

Parallel processing requirements for vaccine submissions to the Pharmaceutical Benefits Advisory Committee (PBAC)

Note: the below requirements are for ATAGI's purposes only and will not be considered as part of the PBAC submission process.

All companies are required to advise the ATAGI Secretariat of their intention to use parallel processing arrangements for vaccine submissions to the PBAC. This should be communicated at the same time that ATAGI pre-submission advice is requested.

In doing so, a company must clearly justify the reason for using parallel processing as well as timeframes for TGA registration. This will enable the Department and ATAGI to consider the company's position when prioritising ATAGI's workload for developing pre-submission advice.

In particular, the following issues should be considered by companies opting to use parallel processing for vaccines:

- Tender timeframes i.e. whether delaying the PBAC submission would affect a company's ability to participate in an upcoming tender.
- The nature of the TGA application i.e. whether it is for a new vaccine or a change to the indication or dose schedule for an existing vaccine.
- The potential public health benefit of including the new vaccine (or the change in schedule and/or indication to an existing vaccine) on the NIP.
- The potential benefits of having an additional supplier of the vaccine type on the NIP to ensure security of supply.

Further information relating to parallel processing requirements for the PBAC is available on the [Pharmaceutical Benefits Scheme website](#).