

Australia issues new information for vaccine manufacturers

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A new process came into effect on 1 July 2020 for sponsors to request advice from ATAGI for vaccines to be listed on the National Immunisation Program.



Vaccine manufacturers seeking listing on the National Immunisation Program (NIP) Schedule must ask for advice from the [Australian Technical Advisory Group on Immunisation \(ATAGI\)](#) before making a submission to the Pharmaceutical Benefits Advisory Committee (PBAC).

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.

Cost recovery arrangements has commenced on 1 July 2020 for Australian Technical Advisory Group on Immunisation (ATAGI) evaluation that supports Pharmaceutical Benefits Advisory Committee (PBAC) consideration of vaccines for the National Immunisation Program (NIP).

As of 1 July 2020, there will be three cycles per calendar year for sponsors to request pre-submission advice from ATAGI, for a vaccine submission to the PBAC.

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.