National Immunisation Program (NIP) vaccine listing process

In order for a vaccine to be supplied through the NIP, the following regulatory steps must occur:

1. TGA Registration

- All vaccines must be registered by the Therapeutic Goods Administration (TGA) as clinically safe and effective for use in Australia.
- *A positive TGA delegate's overview must be provided in order for the Pharmaceutical Benefits Advisory Committee (PBAC) to consider recommending a submission (refer Step 2).*
- *Full TGA registration is required before Government approval can be sought to fund a vaccine for a particular cohort through the NIP (refer Step 4).*

2. PBAC recommendation

- All new vaccines and extended cohorts for existing NIP vaccines must be recommended by the PBAC as clinically and cost-effective for the NIP.
- *Clinical advice from ATAGI must accompany all vaccine submissions to the PBAC and submissions must address all matters raised in the ATAGI advice where appropriate (refer to information on ATAGI pre-submission advice below). For further information regarding the PBAC process please refer to the PBAC Guidelines (https://pbac.pbs.gov.au).*

3. Price agreement

- Following a positive PBAC recommendation, a price must be agreed between the Department and the pharmaceutical company.
- *There will be opportunity for further price negotiations as part of the NIP vaccine procurement process (refer Step 6).*

4. Government approval

- Following full TGA registration and a positive PBAC recommendation, the Department must seek Government approval to fund a new vaccine for a particular cohort through the NIP.
- *Actual purchasing arrangements are subject to the outcomes of a NIP vaccine procurement process - no vaccine is guaranteed to be purchased for supply on the NIP (refer Step 6).*

5. Listing on Determination

- Following Government approval, a vaccine must be listed on the *National Health (Immunisation Program - Designated Vaccines) Determination 2014 (No. 1)* (the Determination).
- *All amendments to the Determination are registered on the Federal Register of Legislation (https://www.legislation.gov.au/).*

6. Vaccine Procurement

- Following a positive PBAC recommendation, a company is eligible to participate in a procurement process to have that vaccine purchased by the Government for supply through the NIP.
- *A vaccine must be approved by Government and listed on the Determination before any contract for supply can be executed.*