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The Australian model of immunization advice and vaccine funding

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ABSTRACT

The Australian Government has implemented new arrangements for public funding of vaccines over the past 5 years. By utilising the standard Pharmaceutical Benefits Advisory Committee (PBAC) application process, whether for funding under the National Immunisation Program Schedule (NIP) or under the Pharmaceutical Benefits Scheme (PBS), a predictable and transparent process for vaccine funding recommendations has been established. This process uses the high-level technical resources available through the Australian Technical Advisory Group on Immunisation (ATAGI) to ensure that both vaccine manufacturers and the PBAC are optimally informed about all relevant aspects of population benefits and delivery of vaccines. ATAGI has a long-standing and mutually beneficial dialogue with State and Territory Governments, providers, and vaccine manufacturers to ensure that pipeline awareness, supply issues, and all relevant scientific and clinical details are well understood.

1. Background

In the last 25 years, there has been a 'second-wave' explosion in the availability of new vaccines resulting from protein conjugates, acellular approaches, new molecular strategies and adjuvants. This bounty of safe and effective vaccines has created the potential for substantial gains in the prevention, high-level control and even near-eradication of hitherto commonplace, life-threatening and disabling diseases. However, this potential cannot be realized without effective funding mechanisms to provide free or at least affordable vaccines to the population. Australia, with a population of about 22 million, is governed at three levels: a Commonwealth (or federal) Government; six state Governments (New South Wales, Victoria, Queensland, Western Australia, South Australia and Tasmania) and two major mainland territories (the Northern Territory and the Australian Capital Territory [ACT]); and local governments at municipal level within these states and territories. The national policy for public immunisation in Australia, the Immunise Australia Program, aims to increase national immunisation rates by funding free vaccination programs, administering the Australian Childhood Immunisation Register and communicating information about immunisation to the general public and health professionals. The policy takes account of the shared responsibilities of the Commonwealth, States and Territories and municipalities. The free vaccination programs are listed under the National Immunisation Program (NIP) Schedule (Fig. 1) (http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/nips2). Funding for essential vaccines alone was well in excess of $AU400m during the 2008–2009 financial year. The Commonwealth also provides funding to the States and Territories to deliver immunisation programs in their respective jurisdictions.

In the 1990s, recommendations for public funding of vaccines for the Australian mass immunisation schedule came from an expert sub-committee within the National Health and Medical Research Council's (NHMRC) advisory committee structure. This sub-committee was responsible for the National Immunisation Handbook (the Handbook)—the Government-produced national clinical guidelines aimed at all health professionals. These clinical guidelines were not directly connected to Government vaccine funding decisions. In 1997, the Government decided to bring this advisory function inside the Department of Health and Ageing (DoHA) and remove it from under NHMRC governance by creating

Abbreviations: ACT, Australian Capital Territory; ADEC, Australian Drug Evaluation Committee; ADRAC, Adverse Drug Reactions Advisory Committee; ATAGI, Australian Technical Advisory Group on Immunisation; AWP, ATAGI Working Party; CDNA, Communicable Diseases Network Australia; COAG, Council of Australian Governments; DoHA, Department of Health and Ageing; MAVIG, Medicines Australia Vaccine Industry Group; NCIRS, National Centre for Immunisation Research and Surveillance; NHMRC, National Health and Medical Research Council; NIC, National Immunisation Committee; NIP, National Immunisation Program; PBAC, Pharmaceutical Benefits Advisory Committee; PBPA, Pharmaceutical Benefits Pricing Authority; PBS, Pharmaceutical Benefits Scheme.

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the Australian Technical Advisory Group on Immunisation (ATAGI) under the Minister for Health, with essentially the same functions as the former NHMRC sub-committee. However, the provision of advice function was narrowed to provide confidential advice to the Minister.

In 2005, the Government introduced legislation to bring vaccine funding applications into the same transparent and predictable mechanism that had been used successfully for drugs. The Australian Pharmaceutical Benefits Scheme (PBS) has a long history of acceptability to Government and to industry, with an effec-

Australian Government
Department of Health and Ageing

National Immunisation Program Schedule

(VALID FROM 1 JULY 2007)

Age	Vaccine
Birth	• Hepatitis B (hepB) [a]
2 months	• Hepatitis B (hepB) [b] • Diphtheria, tetanus and acellular pertussis (DTPa) • *Haemophilus influenzae type b (Hib)* [c,d] • Inactivated poliomyelitis (IPV) • Pneumococcal conjugate (7vPCV) • Rotavirus
4 months	• Hepatitis B (hepB) [b] • Diphtheria, tetanus and acellular pertussis (DTPa) • *Haemophilus influenzae type b (Hib)* [c,d] • Inactivated poliomyelitis (IPV) • Pneumococcal conjugate (7vPCV) • Rotavirus
6 months	• Hepatitis B (hepB) [b] • Diphtheria, tetanus and acellular pertussis (DTPa) • *Haemophilus influenzae type b (Hib)* [c] • Inactivated poliomyelitis (IPV) • Pneumococcal conjugate (7vPCV) [e] • Rotavirus [j]
12 months	• Hepatitis B (hepB) [b] • *Haemophilus influenzae type b (Hib)* [d] • Measles, mumps and rubella (MMR) • Meningococcal C (MenCCV)
12-24 months	• Hepatitis A (Aboriginal and Torres Strait Islander children in high risk areas) [f]
18 months	• Varicella (VZV)
18-24 months	• Pneumococcal polysaccharide (23vPPV) (Aboriginal and Torres Strait Islander children in high risk areas) [g] • Hepatitis A (Aboriginal and Torres Strait Islander children in high risk areas)
4 years	• Diphtheria, tetanus and acellular pertussis (DTPa) • Measles, mumps and rubella (MMR) • Inactivated poliomyelitis (IPV)
10-13 years [h]	• Hepatitis B (hepB) • Varicella (VZV)
12-13 years [i]	• Human Papillomavirus (HPV)
15-17 years [i]	• Diphtheria, tetanus and acellular pertussis (dTpa)
15-49 years	• Influenza (Aboriginal and Torres Strait Islander people medically at-risk) • Pneumococcal polysaccharide (23vPPV) (Aboriginal and Torres Strait Islander people medically at-risk)
50 years and over	• Influenza (Aboriginal and Torres Strait Islander people) • Pneumococcal polysaccharide (23vPPV) (Aboriginal and Torres Strait Islander people)
65 years and over	• Influenza • Pneumococcal polysaccharide (23vPPV)

* Please refer to reverse for footnotes

IMMUNISATION

Fig. 1. The Australian National Immunisation Program Schedule.

Footnotes to National Immunisation Program Schedule

a Hepatitis B vaccine should be given to all infants as soon as practicable after birth. The greatest benefit is if given within 24 hours, and must be given within 7 days.

b Total of three doses of hepB required following the birth dose, at either 2m, 4m and 6m or at 2m, 4m and 12m.

c Give a total of 4 doses of Hib vaccine (2m, 4m, 6m and 12m) if using PRP-T Hib containing vaccines.

d Use PRP-OMP Hib containing vaccines in Aboriginal and Torres Strait Islander children in areas of higher risk (Queensland, Northern Territory, Western Australia and South Australia) with a dose at 2m, 4m and 12m.

e Medical at-risk children require a fourth dose of 7vPCV at 12 months of age, and a booster dose of 23vPPV at 4 years of age.

f Two doses of hepatitis A vaccine are required for Aboriginal and Torres Strait Islander children living in areas of higher risk (Queensland, Northern Territory, Western Australia and South Australia). Contact your State or Territory Health Department for details.

g Contact your State or Territory Health Department for details.

h These vaccines are for one cohort only within this age range, and should only be given if there is no prior history of disease or vaccination. Dose schedules may vary between jurisdictions. Contact your State or Territory Health Department for details.

i This vaccine is for one cohort only within this age range. Contact your State or Territory Health Department for details.

j Third dose of vaccine is dependent on vaccine brand used. Contact your State or Territory Health department for details

Further information

Further information and immunisation resources are available from the Immunise Australia Program website at **www.immunise.health.gov.au** or by contacting the infoline on **1800 671 811**.

You should contact your State or Territory health department for further information on the program specific to your State or Territory:

State/Territory	Contact Number
Australian Capital Territory	02 6205 2300
New South Wales	Public Health Unit (look under 'Health' in the White Pages)
Northern Territory	08 8922 8044
Queensland	07 3234 1500
South Australia	08 8226 7177
Tasmania	03 6222 7724 or 1800 671 738
Victoria	1300 882 008
Western Australia	08 9321 1312

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Fig. 1. (*Continued*).

tive methodology to minimise price and to standardise a decision framework using cost-effectiveness evaluation based on a price per disability- or quality-adjusted life year saved. These new arrangements have produced a high quality policy framework that has supported the introduction and public funding of many new vaccines. Ultimately, however, as with all countries, the capacity to pay regardless of future health savings is an immediate issue for governments that is constrained by the availability of funds drawn from the public purse that must support the full range of government commitments, both within and beyond the health sector.

2. ATAGI terms of reference, relationships and membership

2.1. The terms of reference of ATAGI

The terms of reference of ATAGI are to:

- provide technical advice to the Minister for Health and Ageing on the medical administration of vaccines available in Australia, including those on the NIP;
- advise the Pharmaceutical Benefits Advisory Committee (PBAC) on matters relating to the ongoing strength of evidence pertaining to existing, new and emerging vaccines in relation to their effectiveness and use in Australian populations;
- produce the Australian Immunisation Handbook for the approval of the NHMRC;
- consult with the National Immunisation Committee (NIC) on the content and format of the Australian Immunisation Handbook and implementation strategies; and
- consult with the Communicable Diseases Network Australia (CDNA), the Australian Drug Evaluation Committee (ADEC) and the Adverse Drug Reactions Advisory Committee (ADRAC) on matters relating to the implementation of immunisation policies, procedures and vaccine safety.

2.2. ATAGI and its relationship to other advisory bodies

There are a number of collaborating agencies that interact with ATAGI in the provision of advice and the formulation of policy and funding decisions (Fig. 2). The National Centre for Immunisation Research and Surveillance (NCIRS) of vaccine-preventable diseases, funded by the Australian Government, plays a major role in supporting ATAGI and its working parties, described below. Formal responsibility for vaccine safety monitoring resides with the ADRAC of the Therapeutic Goods Administration. The PBAC plays a key role, described below, in making vaccine funding recommendations to Government, based on the manufacturer's submission, ATAGI advice and other expert health economic inputs. The NIC chaired by the Australian Government, is comprised of State and Territory Government immunisation directors plus members from the medical and general practice community, NCIRS and consumers. Its role is to coordinate a national approach to immunisation delivery and to provide a forum for communication with the Commonwealth. ATAGI works closely with NIC to ensure that vaccine utilisation advice takes full account of program delivery matters. A number of the committees listed in Fig. 2 have consumer representation.

2.3. Relationship with the National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) is Australia's principal body for supporting health and medical research (http://www.nhmrc.gov.au/); for developing health advice for the Australian community, health professionals and governments (http://www.nhmrc.gov.au/guidelines/health_guidelines.htm); and for providing advice on ethical behaviour in health care and in the conduct of health and medical research. In relation to health advice, the NHMRC endorses and provides quality assurance for a wide range of medical bodies' recommendations, including ATAGI's advice on immunisation and the production of the Australian Immunisation Handbook (http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/Handbook-home). While ATAGI is responsible for production of the Handbook, it must adhere to NHMRC guidance on guideline development, including the use of levels of evidence and systematic reviews (http://www.nhmrc.gov.au/publications/synopses/cp30syn.htm). NHMRC is also bound by Government regulation to ensure that all its endorsed advice goes through a formal process of public consultation and feedback. This process is managed through the National Institute for Clinical Studies (NICS), an agency of the NHMRC tasked with quality control and dissemination of clinical guidelines in Australia (http://www.nhmrc.gov.au/nics/index.htm).

2.4. ATAGI membership

Members are appointed by the Minister of Health through an informal nomination process for a term of 4 years, with the possibility of reappointment for 2 years or longer at the Minister's discretion. Membership is defined by expertise in the following categories: public health or practice nursing with expertise in vaccination procedures; general practice (private and pubic sector); public health; expertise in the use of vaccines and immunobiologic agents in clinical practice or preventive medicine; clinical or laboratory vaccine research; expertise in the assessment of vaccine efficacy and safety; consumer expertise; adult infectious diseases; or microbiology. One member is a member in common with the PBAC. *Ex officio* members include: Assistant Secretary, Immunisation Branch, (Office for Health Protection) DoHA; Director, Drug Safety and Evaluation, Therapeutic Goods Administration; representative from the NIC; representative from the CDNA; and Director of the NCIRS of vaccine-preventable diseases.

2.5. Declaration of interests of ATAGI members

Members make formal annual written declarations of interest to the Government. Prior to each meeting, a detailed agenda is circulated to all members who identify up to date and current potential conflicts of interest for each agenda item, providing detail of the conflict. The Chair in consultation with the Government officers makes a determination as to whether the member can participate in discussion on the item, contribute factual information if required, remain in the room but silent, or be excluded from the room for items where a potential for conflict exists. In general, personal remuneration of other forms of direct or indirect financial or other benefits for marketing or promotional activities are inconsistent with ATAGI membership. The decision points around determinations of how declared conflicts will be managed are not always absolute and may evolve over time. Regular discussion between the chair of ATAGI and the chair of PBAC and with members of Government is conducted to review specific issues as they arise. Australia with a small population, has a limited pool of highly expert individuals, and their involvement with industry in clinical research is regarded positively. Therefore, involvement in industry-sponsored vaccine research where payment is made to an institution and not to the individual is generally not considered a conflict requiring exclusion, and a member may be involved in discussion or provision of factual information. Conflicts may involve the Chair and may require that the Chair vacate their position for a specific discussion or decision on a recommendation if judged by Government officers to be required. ATAGI Working Party (AWP) members must also abide by these rules (see below).

3. Process for new vaccine recommendations

The ATAGI provides technical advice on vaccines well before licensure of a new vaccine (Fig. 3). Early and open communication between the vaccine manufacturer and the Australian regulator (Therapeutic Goods Administration) is essential, and several mechanisms described below have been built into the process to ensure that this occurs. The process for informing Government's decision

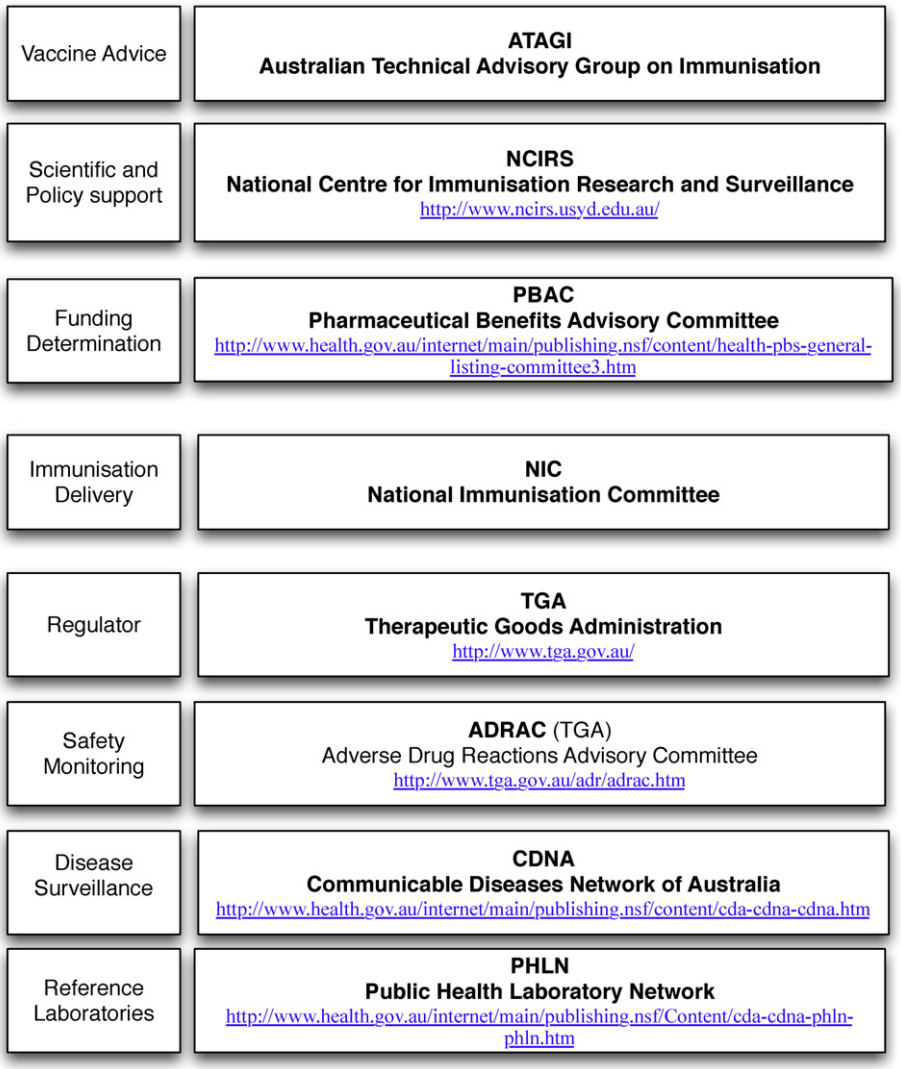

Fig. 2. ATAGI and other statutory or advisory bodies contributing to vaccine policy and decision-making.

on whether or not to fund a new vaccine under the NIP or the PBS proceeds in a number of phases.

3.1. ATAGI scoping phase

A continuous process of 'horizon scanning' is conducted by ATAGI to forecast impending licensure of new vaccines. Formal interaction with vaccine manufacturers via an annual industry day contributes importantly to this, giving manufacturers an opportunity to provide an 'in-confidence' briefing on their development, trialling and registration submission plans. ATAGI establishes a sub-committee, an AWP, far ahead of the anticipated time of a new vaccine licensure and subsequent PBAC submission by the company. A detailed and structured document is produced by the AWP for ATAGI consideration. Following any necessary modification, a PBAC pre-submission advice is compiled based on an agreed framework developed jointly by ATAGI and the PBAC, and reflects the key points outlined in the Vaccine Appendix of the PBAC process. This process considers issues related to the suitability of including a new vaccine into the NIP including: implications for herd immunity (neither necessary nor sufficient for a positive recommendation for NIP suitability); general or targeted immunisation; need for catch-up program; schedule issues (dosing, boosters, fit with existing NIP vaccines); alternatives to vaccine; clinical uncertainties and special considerations; requirements for implementation and likely consequences for other patterns of resource provision related to the NIP; and any other relevant considerations (http://www.health.gov.au/internet/main/publishing.nsf/Content/AECB791C29482920CA25724400188EDB/$File/PBAC4.3.2(01DEC08).pdf). In some specific circumstances, a possible alternative to NIP listing is a co-funding arrangement (the patient/consumer pays a subsidised proportion of the full cost) under the PBS as applies to publically funded drugs that are prescription-based.

3.2. PBAC phase

The ATAGI Pre-submission Advice is provided to both PBAC and to the submitting company (known as the sponsor). This process is designed to ensure that the vaccine manufacturer fully understands the formal public health and technical considerations that are material to the public interest, with the exception of cost-effectiveness, which is the province of PBAC. Following submission of a company's application to the PBAC for NIP or PBS listing of a vaccine, preliminary evaluation by the PBAC Secretariat with key PBAC members may result in further questions to ATAGI regarding a range of matters pertaining to the submission. This may include a request to verify a claim made in the dossier (for example, regarding

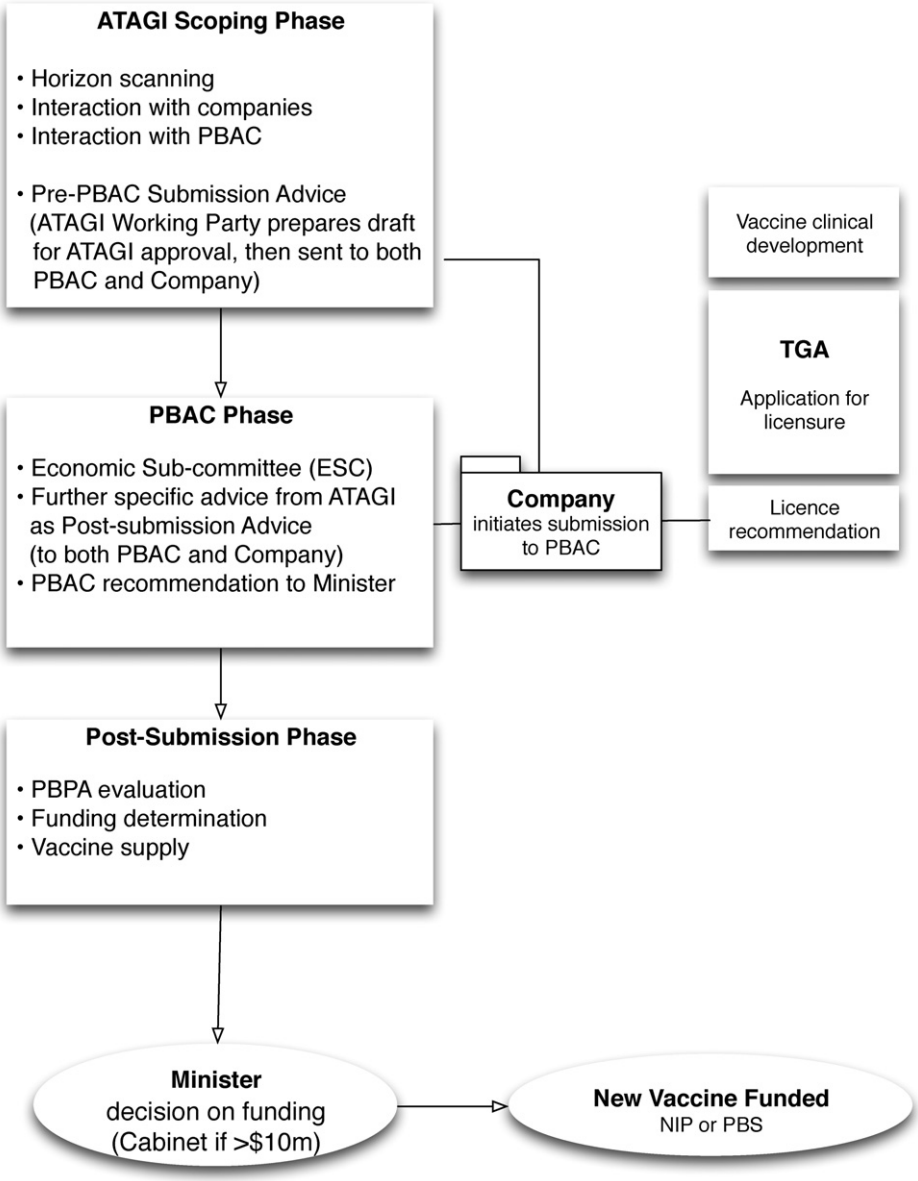

Fig. 3. Process for public funding of vaccines.

an immunologic correlate of protection), or to clarify interpretation of a specific piece of evidence. In response to a formally communicated set of questions copied to the manufacturer, the AWP prepares a post-submission advice that is presented to ATAGI for modification if required and endorsement. This advice is then communicated to the PBAC and copied to the manufacturer. Parallel to this, a detailed commentary on the sponsor's submission is prepared for the PBAC by a consultant under contract to the Department of Health. The PBAC also has an Economic Sub-committee (ESC) that reviews and interprets the economic analyses in these submissions and provides written advice. Both of these documents are also copied to the manufacturer, which has an opportunity to respond. Formal determination on the application is then made by the PBAC. This process, its assumptions and economic principles remains subject to some continuing debate and discussion [1–3], but is widely accepted by industry, and healthcare professionals.

3.3. Post-submission phase

Funding decisions for vaccines are made by the Government. If PBAC makes a positive recommendation the Government is not obliged to fund a new vaccine, but the Government cannot fund a vaccine without a positive recommendation from PBAC. There is no time limit set for the Government to make its funding decision. Price negotiation is handled by the Australian Government's Pharmaceutical Benefits Pricing Authority (PBPA, http://www.health.gov.au/internet/main/publishing.nsf/Content/pbs-pbpa-policies-contents~pbs-pbpa-policies-intro).

3.4. Development of recommendations and the basis for decision-making

The ATAGI has a formal process for establishing AWPs including specific terms of reference, an expected end point, and membership. All AWPs are chaired by an ATAGI member, and depending on the issue, may be co-chaired by the senior representative from another statutory group such as CDNA or NIC, depending on the issue. Membership is always expertise-based, and may involve other ATAGI members, NIC members, and experts in a specific area who are not members of ATAGI provided they are free of high-level conflicts of interest. In this last case, where unique outside

expertise is required, an invitation to submit technical material or other advice may be sought, but they cannot be an active member of the AWP. AWPs are supported by one or more scientific officers from the NCIRS who are responsible for assembling the written report, obtaining resource materials and conducting further analysis if required. Crucial to the quality and timely delivery of high quality advice to Government and to providers is the policy branch of the NCIRS. (http://www.ncirs.usyd.edu.au/).

3.5. Role played by the Pharmaceutical Benefits Advisory Committee (PBAC)

Since 2005, the vaccine funding advisory framework in Australia was changed to bring vaccines into the overall policy framework that has been used for drugs for some years. The PBAC was established to consider submissions, usually from manufacturers, based on cost-effectiveness applications for pharmaceuticals or new vaccines. The Chair of the PBAC is appointed full-time, but the Committee's membership is otherwise made up in a similar way to that of the ATAGI, with clinicians, academics and others with particular expertise. PBAC meets three times annually to consider submissions, and then provides a recommendation to Government on whether or not to fund and on what basis. In the case of vaccines, the sponsor may submit for either NIP listing (free to eligible people and listed on the NIP), or PBS listing (requires a co-payment, and is not listed on the NIP).

3.6. Criteria for NIP listing

In Australia, the general criteria for suitability for listing on the NIP are defined in the Vaccine Appendix of the PBAC submission framework (Table A.1).

4. Role of industry, and other private and professional interest groups

Medicines Australia is the umbrella group representing pharmaceutical manufacturers in Australia, and its sub-committee the Medicines Australia Vaccine Industry Group (MAVIG), is a consortium of vaccine manufacturers. MAVIG has played an important role in coordinating the industry view of national policy matters in industry's representation to Government. It played a key role in the consultation and development phase of the vaccine appendix to the PBAC guidelines (Table A.1). ATAGI conducts formal 'in camera' consultations with vaccine manufacturers annually (ATAGI Industry Days) at which companies separately present their latest developments and plans for vaccines. This has proved to be an important two-way communication process to permit ATAGI to plan its working party activities and to coordinate with PBAC for pre-submission advice for upcoming submissions. The process also permits industry to canvas ATAGI views on public health and other relevant perspectives on their products, including scheduling issues, technical matters pertaining to assumptions or data inputs to cost-effectiveness analyses, and many other matters.

The NHMRC-mandated requirement for full public consultation relating to clinical guidelines ensures complete and open access to potential recommendations made by ATAGI. Regular input is received from the professional colleges and unions, consumer groups, state and local government, clinicians and public health workers. However, they do not actively participate in ATAGI discussions, and ATAGI does not conduct open forums.

5. Future developments

ATAGI produces highly detailed and structured AWP reports for new vaccines that form the basis for PBAC submission advice and the content of the Australian Immunisation Handbook. These reports are informed by published and unpublished clinical trials and other up to date evidence, some of which is submitted by the vaccine manufacturer as outlined above. Because of restrictions on releasing as yet unpublished clinical trial data, or other commercial restrictions by the companies, unabridged AWP reports are not made public. A process to refine these reports to address these restrictions to permit their public airing in a timely fashion is under consideration.

The Australian Government will develop a new National Immunisation Strategy in 2010. A process of wide stakeholder consultation will precede the strategy development. A number of key issues will be canvassed with stakeholders such as vaccine supply, efficacy and quality, education and workforce development, surveillance and research development, data systems, service delivery, and governance arrangements.

In early 2008, the Council of Australian Governments (COAG) representing all the State and Territory Governments of the Commonwealth, agreed to the direct purchasing of essential vaccines, under the National Immunisation Program by the Commonwealth, which commenced from 1 July 2009. The precise arrangements to facilitate this new process will be based on the National Partnership Agreement on Essential Vaccines that is available at http://www.federalfinancialrelations.gov.au.

6. Conclusion

The Australian approach to vaccine policy development (including vaccine funding decision-making) is a multi-part activity that attempts to bridge federal and state roles and responsibilities with high-quality scientific foundations embedded in a national health funding model that is founded on equity of access for all. As the cumulative price for publically funded vaccines climbs, competitive pressure for access to the financial investment required to deliver the potential health service savings and health outcome return must have a solid basis in clinical and public health evidence. Trading off competing demands of commercial priorities, access to population markets, transparency of process, and a level playing field are all elements to be built into this framework. Continued improvement of all aspects of the model, including the way the ATAGI functions, is essential to maintain relevance in the changing global environment.

Appendix A.

See Table A.1.

Table A.1
Vaccine Appendix of the Pharmaceutical Benefits Advisory Committee (Extracted from page 221 of http://www.health.gov.au/internet/main/publishing.nsf/Content/AECB791C29482920CA25724400188EDB/$File/PBAC4.3.2(01DEC08).pdf.

Several factors affect whether vaccines will be listed on the PBS or be funded under the NIP. A vaccine should generally be proposed for funding under the NIP where there is expected to be an additional health benefit to the community beyond the individuals vaccinated, which would be improved by maximising coverage rates of the proposed vaccine in the identified individuals. More specific considerations favouring a submission for NIP funding include the following:

- The target for the proposed vaccine is a broader population in which there is either no need to assess risk factors for the disease in each individual, or the assessment of risk factors at an individual level is straightforward (e.g. age, sex, ethnicity, geography).
- There is a reason to maximise population coverage of the proposed vaccine because the proposed vaccine reduces one or more of:
  - the proportion of susceptible individuals
  - carriage of the pathogen(s) affected by the vaccine
  - transmission of the infection (including nosocomial infections or reducing the rate or extent of spread of infections in other institutional settings, such as child care centres, schools or nursing homes).
  - Integral to these specific considerations are as follows:
    - The proposed vaccine protects against a new infection or reactivation of an existing infection.
    - The efficacy of the proposed vaccine is sufficient to achieve one or more of the reductions identified in the second bullet point, above (e.g. reductions in the proportion of susceptible individuals, carriage of the pathogen affected by the vaccine, or transmission of the infection).
    - The disease is sufficiently severe or prevalent in an unimmunised population to justify maximising the use of the proposed vaccine in order to achieve its full community health benefit.
    - The proposed vaccine needs only to be delivered as a single dose or a few doses.

An additional factor that might be considered in supporting a request for funding under the NIP is the existence of claimed advantages of increasing herd immunity, particularly where those advantages are supported by clinical evidence (see additional requests below in relation to Part II, Subsection D.3 for the presentation of such advantages and evidence).

PBS listing might be favoured when the proposed vaccine is 'discretionary' for the majority of the population (e.g. to vaccinate an individual against a disease that is not sufficiently prevalent in Australia to justify maximising the use of the proposed vaccine), or the assessment of risk factors is less straightforward (e.g. an assessment of immune system status is required).

Conflict of interest statement

The authors state that they have no conflict of interest.

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