



The Publicly Funded Vaccines Market in Australia

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http://www.bundesgesundheitsministerium.de/cln_160/nn_1168248/SharedDocs/Publikationen/DE/Forschungsberichte/gutachten-impfstoffe,templateld=raw,property=publicationFile.pdf/gutachten-impfstoffe.pdf

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1. Background and Institutional Overview

1.1. Features of the Australian health care system

Australia has a federal system of government. The Constitution of Australia, formally agreed to in 1901, specifies the division of powers between the Australian and State/Territory governments.¹ Within the health sphere, Section 51 of the Constitution assigns only the responsibility for quarantine to the Commonwealth. This leaves the public provision of any other health services as the responsibility of the States, and the organisation of health care reflects this. For example, the States own all public hospitals and they have the main role in providing public hospital services, community and public health services including vaccination programmes (although they do devolve some of these responsibilities to local governments that, as a result, offer vaccination through clinics such as maternal and child health clinics).

However, while States dominate in the public provision of health services, public funding for health care is shared between the Australian Government and the State governments. The overall split of total health care funding in Australia was, in the 2007/08 financial year:

- Australian Government 43.2%
- State and local government 25.5%
- Private (including insurance) 31.3%

(Source: Department of Health and Ageing 2010)

The health care delivery system is complex, with services provided by both public and private sector organisations. Around 60% of hospital separations are from public hospitals and the remainder from private hospitals. The vast bulk of primary care and out-of-hospital specialist care is provided by private general medical practitioners (primary care physicians) and specialists.

The Australian health care system aims to provide universal access to health care for residents of the country. This is achieved via 'Medicare', a compulsory insurance system financed largely by general taxation revenue. The Medicare scheme combines:

- The Medicare Benefits Schedule that provides residents of Australia with access to privately provided medical services and may include co-payments by users where the cost of services is not fully covered by the rebate.
- The Pharmaceutical Benefits Scheme —subsidization of a wide range of prescription medications supplied by community pharmacies.

¹ Australia has six States and two Territories. Within the last few decades, the Territories, which used to be administered by the Commonwealth government, have been granted self government and now function in the same way State governments. In this report, unless otherwise indicated, the term 'State' should be taken to refer to both the States and the Territories.

- Funding provided to Australia's States to assist them in providing access to public hospital services. The States pay for the rest of these services. In return for this funding, the States have agreed to provide inpatient treatment to public patients free of charge.

In addition to Medicare, the Australian national government also provides subsidies to people paying for private health insurance. Every Australian can elect to be treated as a private patient in a public hospital in order to have a choice of doctor. In addition, private hospitals provide an alternative to the public hospital system for many procedures.

The populations of Australia's States and Territories, including a number of small island territories, are shown in Table 1. There is wide variation in the sizes of populations between the States.

Table 1: Australian Population (2009 mid-year)

	Population	% of Australian total population
New South Wales	7.100m	32.5%
Victoria	5.428m	24.8%
Queensland	4.407m	20.1%
Western Australia	2.237m	10.2%
South Australia	1.623m	7.4%
Tasmania	0.503m	2.3%
Australian Capital Territory	0.351m	1.6%
Northern Territory	0.225m	1.0%
Total*	21.875m	

* Includes Jervis Bay Territory, Christmas Island and the Cocos (Keeling) Islands

Source: Australian Bureau of Statistics. Australian Demographic Statistics June 2009

Of particular relevance to this study, the Australian Government is responsible for financing the National Immunisation Program and determining the vaccines to be listed under the programme. Listed vaccines are provided free of charge, i.e. they are 100% publicly funded. Private sector immunisations are, in Australia, mainly focused on providing travel vaccines and vaccines not covered by the national health insurance scheme, e.g. seasonal flu vaccines to non-high risk groups of the population. The private vaccines market is relatively small and is not discussed further here.

1.2. The national immunisation programme and how vaccines reach patients

For a vaccine to be sold legally in the Australian market, approval must be obtained from the Therapeutic Goods Administration, a Commonwealth government (i.e. national rather than state level) organisation. Approval results in the vaccine being listed on the Australian Register of Therapeutic Goods. This allows the vaccine to be sold privately in Australia, i.e. where the consumer pays the full price out of their own pocket. Travel vaccines are sold in this way, as is influenza vaccine for people aged under 65 and not deemed 'at risk'. Additional steps are required before a vaccine can be publicly funded or subsidised.

Vaccines included within the National Immunisation Program are free to the patient. The vaccines listed under the National Immunisation Program are determined by the Department of Health and Ageing (DoHA) of the (national) Australian Government. The current schedule of vaccines, since 1st July 2007, under the Australian National Immunisation Program is shown in Figure 1.

There is no legal obligation for children to be immunised.

Vaccines not included in the National Immunisation Program may be available as part of the Pharmaceutical Benefits Scheme (PBS), which covers medicines and vaccines used on an outpatient basis (i.e. outside hospitals) and supplied through community pharmacies. Vaccines provided under the PBS are: pneumococcal vaccine for adults aged under 65 and diphtheria and tetanus vaccine for all adults (Pharmaceutical Benefits Scheme, 2010). Medicines and vaccines listed on the PBS schedule qualify for a subsidy from the Commonwealth government. General patients who are prescribed a vaccine on the PBS have to pay the first Aus\$33.30 towards the cost of a prescription for a listed medication (a front-end deductible). The front-end deductible for a concessional patient (e.g. aged 65 or over) is Aus\$5.40. The government pays the difference between the front-end deductible and the full price of the prescribed drug, the full price being negotiated by the government with the drug company.

Nationally, the majority, around 70%, of vaccinations are administered by staff at GPs' (general medical practitioners, i.e. primary care physicians working in the community) practices. The other 30% are administered in schools or maternal/child health clinics. The split between types of location varies from State to State, however, ranging from around 55/45 in Victoria to as much as 90/10 elsewhere in New South Wales (source: interviews).

Total government expenditure on vaccines was reported to be Aus\$288 million (approx €170m at the end-September 2004 exchange rate) in 2004/05, (source: presentation by T Nolan, Chair of the Australian Technical Advisory Group on Immunisation, July 2006, available at: <http://www.medicinesaustralia.com.au/pages/images/Terry%20Nolan.pdf> accessed 23 March 2010). The total Commonwealth funding allocated for purchase of essential vaccines in 2009/10 financial year is Aus\$311 million (approx €190m at the end-September 2009 exchange rate) (source: Schedule D of COAG 2009).

Figure 1: Australian National Immunisation Program Schedule (Valid from 1st July 2007)

Age	Vaccine
Birth	<ul style="list-style-type: none"> Hepatitis B (hepB) ^a
2 months	<ul style="list-style-type: none"> Hepatitis B (hepB) ^b Diphtheria, tetanus and acellular pertussis (DTPa) <i>Haemophilus influenzae type b (Hib)</i> ^{c,d} Inactivated poliomyelitis (IPV) Pneumococcal conjugate (7vPCV) Rotavirus
4 months	<ul style="list-style-type: none"> Hepatitis B (hepB) ^b Diphtheria, tetanus and acellular pertussis (DTPa) <i>Haemophilus influenzae type b (Hib)</i> ^{c,d} Inactivated poliomyelitis (IPV) Pneumococcal conjugate (7vPCV) Rotavirus
6 months	<ul style="list-style-type: none"> Hepatitis B (hepB) ^b Diphtheria, tetanus and acellular pertussis (DTPa) <i>Haemophilus influenzae type b (Hib)</i> ^e Inactivated poliomyelitis (IPV) Pneumococcal conjugate (7vPCV) ^f Rotavirus ^g
12 months	<ul style="list-style-type: none"> Hepatitis B (hepB) ^b <i>Haemophilus influenzae type b (Hib)</i> ^h Measles, mumps and rubella (MMR) Meningococcal C (MenCCV)
12-24 months	<ul style="list-style-type: none"> Hepatitis A (Aboriginal and Torres Strait Islander children in high risk areas) ⁱ
18 months	<ul style="list-style-type: none"> Varicella (VZV)
18-24 months	<ul style="list-style-type: none"> Pneumococcal polysaccharide (23vPPV) (Aboriginal and Torres Strait Islander children in high risk areas) ^j Hepatitis A (Aboriginal and Torres Strait Islander children in high risk areas)
4 years	<ul style="list-style-type: none"> Diphtheria, tetanus and acellular pertussis (DTPa) Measles, mumps and rubella (MMR) Inactivated poliomyelitis (IPV)
10-13 years ^h	<ul style="list-style-type: none"> Hepatitis B (hepB) Varicella (VZV)
12-13 years ⁱ	<ul style="list-style-type: none"> Human Papillomavirus (HPV)
15-17 years ⁱ	<ul style="list-style-type: none"> Diphtheria, tetanus and acellular pertussis (dTpa)
15-49 years	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> Influenza (Aboriginal and Torres Strait Islander people) Pneumococcal polysaccharide (23vPPV) (Aboriginal and Torres Strait Islander people)
65 years and over	<ul style="list-style-type: none"> Influenza Pneumococcal polysaccharide (23vPPV)

- 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

Source: Department of Health and Ageing, 2007

1.3. Organisations involved in vaccines policy, evaluation and procurement

The development and implementation of immunisation policy in Australia is led and coordinated by the Population Health Division of the national **Department of Health and Ageing** (DoHA) in Canberra, which is responsible for managing the National Immunisation Program.

The **Australian Technical Advisory Group on Immunisation (ATAGI)** provides advice to the national Minister for Health and Ageing on vaccines and immunisation, including the National Immunisation Program. ATAGI's members are technical experts, clinicians and consumer representatives. ATAGI not only advises the Minister but also the Pharmaceutical Benefits Advisory Committee (see next paragraph), on matters relating to the strength of evidence about the effectiveness of existing, new and emerging vaccines.

Vaccines companies wanting their product to be publicly funded or subsidised can apply for it to be included either in the National Immunisation Program or under the Pharmaceutical Benefits Scheme. In either case, the application, supported by an economic evaluation provided by the sponsor company, will be considered by the **Pharmaceutical Benefits Advisory Committee (PBAC)**. The Committee will advise the Minister for Health on whether to list the vaccine and if so whether on the National Vaccines Schedule of the National Immunisation Program (see Figure 1) or just added to the schedule of vaccines and medicines subsidised under Medicare by the Pharmaceutical Benefits Scheme.

The **Pharmaceutical Benefits Pricing Authority (PBPA)** is an independent non-statutory body established by the Minister for Health and Ageing, with the task of making recommendations to the Minister on the prices of new vaccines and medicines that have been recommended for listing on the Pharmaceutical Benefits Scheme, and of vaccines recommended for inclusion in the National Immunisation Program. The PBPA thereby advises the DoHA in its procurement of, and price negotiations for, medicines and vaccines. The PBPA also reviews these prices annually. The PBPA's overall objective is stated on the DoHA website (<http://www.health.gov.au/>) as: "to secure a reliable supply of pharmaceutical benefits at the most reasonable cost to Australian taxpayers and consumers, consistent with maintaining a sustainable, viable and responsible pharmaceutical industry in Australia." Vaccines are included within the meaning of "pharmaceutical benefits" here. The PBPA makes its price recommendations whatever the specific procurement route, which has changed since mid-2009, as will be explained below.

The **governments of the States and Territories** of Australia (see Table 1) are responsible for ensuring the provision of health care to their residents, including vaccines under the National Immunisation Program and Pharmaceutical Benefits Scheme. Since 1 July 2009, the national Government has taken over responsibility for actually purchasing vaccines under the National Immunisation Program and it now makes them available to the States free of charge for administration to patients in their areas. Prior to July 2009 the State governments purchased the vaccines from amongst those listed under the National Immunisation Program but were

provided with the funds to do so by the Australian Government as agreed to under the Australian Immunisation Agreements which were part of the Commonwealth/State Public Health Outcome Funding Agreements (PHOFAs).

The overall picture in Australia is therefore of a highly centralised approach to determining which vaccines to provide to whom, and the prices paid for them. The process has become even more centralised since 1 July 2009, as since then the national Government has taken over from the State governments the responsibility of procuring vaccines from the supplying companies.

2. Methods of Cost Benefit Analysis of Vaccines

2.1. PBAC and ATAGI

The decision to list a medicinal product on the Australian Register of Therapeutic Goods allows that product to be sold in Australia but does not give access to any public subsidy, and does not guarantee purchase of the product by any public body. The mechanism for a product being given Commonwealth Government subsidy is by way of an application submitted by the sponsor (usually a company) to be considered by the Pharmaceutical Benefits Advisory Committee (PBAC). Submissions have since 1993 been required to include an economic evaluation, making Australia one of the first countries to require economic evidence as a mandatory part of medicines and vaccines funding decisions.

PBAC, an independent statutory body established under the National Health Act 1953, is responsible for recommending to the national Minister for Health and Ageing the medicines and vaccines for subsidy under the Pharmaceutical Benefits Scheme (PBS). Since 2006, PBAC has also been required under the Act to recommend vaccines for listing on the National Vaccines Schedule, which entails funding under the National Immunisation Program (NIP). PBAC's guidelines state that the principles "for considering PBS listing of drug products in general also apply to the funding for vaccines by the NIP" (Department of Health and Ageing 2007).

Members of PBAC, who are appointed by the national Minister for Health and Ageing, include medical practitioners, pharmacists, consumers and health economists. It has an Economics Sub-Committee (ESC) which is responsible for evaluating the cost effectiveness aspects of submissions before they are presented to the main Committee. No new vaccines may be made available through the National Immunisation Program or the PBS in absence of a PBAC recommendation (source: <http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-general-listing-committee3.htm>). The final decision on funding is made by the Minister for Health and Ageing, although it is uncommon for the Minister to deviate from PBAC's recommendations (source: interviews). There is no defined timeline within which the Minister is required to make this final decision.

Another national body that provides advice on vaccines is the Australian Technical Advisory Group on Immunisation (ATAGI), whose membership comprises mainly medical and public health experts. ATAGI pre-dates the PBAC's involvement in vaccine evaluation and had previously been responsible for making recommendations relating to the funding of vaccines under the National Immunisation Program – the role that is now fulfilled by PBAC. Its current terms of reference include the following responsibilities:

- Provide technical advice to the Minister for Health and Ageing on the medical administration of vaccines available in Australia, including those on the National Immunisation Program.

- Advise 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.

(source: <http://www.health.gov.au/internet/immunise/publishing.nsf/content/advisory-bodies>)

An industry interviewee noted that ATAGI continues to have a number of important functions, such as providing pre-PBAC advice to companies on their applications, and clinical advice to PBAC, in particular relating the suitability of including a particular vaccine in the National Immunisation Program and the appropriateness of implementing catch-up programmes (which provide coverage to individuals who could benefit from vaccination at the introduction of a new programme but who are older than the specified age range).

2.2. Outline of the process

When preparing submissions for PBAC's consideration, companies are asked to indicate whether the application is for listing on the Pharmaceutical Benefits Scheme or for funding under National Immunisation Program. In general, a vaccine is a suitable candidate for funding under the National Immunisation Program where there is expected to be an additional health benefit to society beyond the individuals vaccinated, which would be improved by maximising coverage rates.

Specific considerations favouring a submission for National Immunisation Program funding include the following:

- the target is a broader population where there is either no need to assess risk factors for the disease in each individual, or the individual-level risk factor assessment is straightforward;
- there is good reason for maximising population coverage of the vaccine (for example, because the vaccine reduces the transmission of the infection, or because the disease is particularly severe or prevalent in an unimmunised population);
- the vaccine protects against a new infection or reactivation of an existing infection;
- there are likely to be advantages of increasing herd immunity.

Pharmaceutical Benefits Scheme listing, on the other hand, might be favoured in cases where the vaccine is considered discretionary for the majority of the population, or where the assessment of risk factors is less straightforward. It is possible for a vaccine to be listed on the Pharmaceutical Benefits Scheme for one indication whilst being funded under the National Immunisation Program for another (Department of Health and Ageing 2007).

In the case of a negative PBAC recommendation, the vaccine will be neither listed on the Pharmaceutical Benefits Scheme nor funded under the National Immunisation Program.

Companies are given the opportunity to resubmit, and can in principle resubmit as many times as they wish. In practice, however, companies tend to make an effort to avoid the need for resubmission, particularly if they believe that there is a competitor product in the pipeline (source: interviews).

2.3. Details of the economic evaluation process

One of the main mechanisms for determining whether or not a vaccine is given Commonwealth subsidy is PBAC's evaluation of whether it represents 'value for money' for the Australian community. This is achieved by considering the economic information supplied as part of the application. The aim is to evaluate the costs associated with the vaccine against the health benefits gained from its use, and to compare the resultant cost effectiveness ratio with that of its main comparator. This will be an alternative vaccine available on the National Immunisation Programme or Pharmaceutical Benefits Scheme if there is one, or standard medical management if there is not.

PBAC's recommendations are typically made on the basis of either a cost utility analysis (CUA) or a cost minimisation analysis (CMA). In general, CUA, where the health outcome is commonly defined in terms of incremental quality adjusted life years (QALYs) gained, is the preferred type of economic evaluation. However, CMA is also considered appropriate in cases where the proposed vaccine has been shown to be equivalent to the main comparator and there is no claim of clinical superiority. Cost benefit analysis, whereby all outcomes are valued in monetary terms, is acceptable only as a supplementary option. PBAC's Guidelines note that the various types of economic evaluation are not necessarily mutually exclusive and that it may be appropriate to present more than one type (Department of Health and Ageing 2007).

The primary objective of the Pharmaceutical Benefits Scheme and National Immunisation Program is to improve health. PBAC therefore focuses primarily on health outcomes and direct health care costs when evaluating vaccination programmes, although its Guidelines indicate that it may in some cases consider non-health outcomes and indirect costs such as greater convenience or production gains to society. All evaluations should be relevant to the Australian context and examine the likely changes in the provision of health care resources after the introduction of the vaccine, including changes in the provision of resources that are not subsidised through the Pharmaceutical Benefits Scheme or National Immunisation Program.

The economic model will be either static or dynamic. In static models, the force of infection (the probability per unit time that a susceptible person acquires infection) is constant over time and herd immunity effects are ignored. Dynamic models, on the other hand, allow herd immunity and age shift to be assessed, and are considered appropriate when the force of infection is likely to change following immunisation and when the risk or severity of the disease depends on age. PBAC requires submissions to justify the chosen duration of the model, since the cost effectiveness of vaccination programmes typically reaches a plateau after a period of time, and the model's duration should not be limited to a time before that plateau is reached. A real

annual discount rate of 5% is applied to both costs and benefits across the duration of the model. The price assumption used in submissions should refer to the Commonwealth price applying to vaccines funded under the National Immunisation Program rather than the dispensed price with patient co-payments removed that applies to vaccines listed on the Pharmaceutical Benefits Scheme.

A number of aspects of PBAC's evaluation methodology have come under scrutiny. Beutels et al. argue that vaccines warrant a different approach from curative therapies, and call for guidelines for evaluating vaccines to allow for a wider perspective to be used in order to take account of benefits such as improvements in carers' quality of life. They also argue for alternative discounting techniques to deal with social time preference over long time periods and for the routine inclusion of vaccine-specific considerations such as herd immunity benefits (Beutels et al. 2008).

In response to Beutels et al., four individuals who were involved in developing the current PBAC approach replied that such a differential approach for vaccines would lead to "increased prices for vaccines without a sufficient basis to warrant this greater cost" (Mitchell et al. 2009). They claimed that it is reasonable and equitable for vaccines to be assessed using a similar approach to that used for pharmaceuticals and other health technologies, pointing out that issues such as those relating to the inclusion of indirect costs are not unique to vaccines. In addition, they argued that the routine inclusion of special considerations such as herd immunity benefits could delay access since evidence relating to these considerations tends to come from post-marketing studies after funding decisions have already been made. If the data subsequently show that herd immunity exceeds expectations, then there exist mechanisms that allow manufacturers to request an increase in price.

3. How the Outcomes of Cost Benefit Analysis Affect Pricing and Reimbursement

As noted in section 2, the common outcome of the economic evaluation is a comparison of the cost effectiveness of the proposed vaccine with that of its main comparator. If this comparison favours the proposed vaccine, then the evidence can be used to justify a price advantage over the comparator.

If PBAC recommends the listing of a vaccine, and the Minister for Health and Ageing agrees with that recommendation, then the application progresses to the Pharmaceutical Benefits Pricing Authority (PBPA), an independent non-statutory body which is responsible for advising the Minister on prices for new vaccines recommended for inclusion on the National Immunisation Program. The PBPA conducts pricing negotiations with companies, but is not involved in the economic evaluation process and is not accountable for either the clinical or the economic aspects of PBAC's recommendations (source:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-pbs-pbpa-pricing-policiesdoc~pbac-pbpa>).

In considering the price of products recommended for listing and in reviewing the price of products that are already listed, the PBPA takes account of the following factors:

- PBAC advice on clinical and cost-effectiveness;
- prices of alternative products;
- comparative prices of products in the same Anatomical Therapeutic Chemical groups;
- cost information, either provided as part of the submission or estimated by the PBPA;
- volumes, economies of scale, special storage requirements, product stability, special arrangements;
- level of activity being undertaken by the company in Australia, including new investment, production, research and development (not presently taken into consideration when recommending prices);
- prices in reasonably comparable overseas countries;
- other factors the applicant may wish the PBPA to consider;
- any directions of the Minister.

(source: <http://www.nhhrc.org.au/internet/main/publishing.nsf/Content/health-pbs-pbpa-pricing-policiesdoc~pbpa-factors>)

When resubmitting an application for listing following a negative PBAC recommendation, it is not uncommon for manufacturers to offer a reduced price in order to increase the likelihood of their product being deemed cost effective second time around. A recent example of this is the case of the rotavirus vaccine, RotaTeq. In July 2006, PBAC rejected the submission to list RotaTeq on the National Immunisation Program because of “uncertain cost effectiveness at the price requested” (PBAC 2006a). Some of these uncertainties related to the model itself – for example, the model included production gains, which PBAC indicated that it had not previously accepted in base case analyses for decision making purposes. The manufacturer’s November 2006 resubmission made a number of changes that addressed the key modelling uncertainties and also included a reduced requested price. After considering the resubmission, PBAC recommended the inclusion of RotaTeq for funding under the National Immunisation Program on the basis of “acceptable cost effectiveness” (PBAC 2006b). The change in decision is likely to have been at least in part driven by the reduction in the price offered by the company.

Another example of a situation where the results of the economic evaluation clearly influenced pricing and reimbursement decisions is the case of the quadrivalent HPV vaccine, Gardasil. Roughead et al. describe how the initial decision to reject funding Gardasil caused considerable public and political outcry, much of which related to a “misunderstanding of the decision making process, particularly cost effectiveness assessments” (Roughead et al. 2008). On 8th November 2006, PBAC announced that it had not recommended Gardasil for funding under the National Immunisation Program. One of the reasons given for the decision was that it was “not cost effective for taxpayers at this time to fund Gardasil on the National Immunisation Program at the price proposed” (Australian Government Department of Health and Ageing 2006a).

The company, CSL, was asked to make a minor resubmission to PBAC addressing the areas of dispute. The resubmission was considered at an extraordinary PBAC meeting on 22nd November 2006, and a few days later it was announced that Gardasil would be put on the National Immunisation Program following CSL’s agreement to reduce its price and to provide PBAC with additional information about its long term effectiveness. The announcement stated that “PBAC found that Gardasil is cost effective at the new price offered” (Australian Government Department of Health and Ageing 2006b). The public summary document clearly states that PBAC considered that the price reduction, which resulted in a more favourable incremental cost effectiveness ratio, was central to its decision (PBAC 2006c).

Roughead et al. (2008) describe how PBAC was bound by commercial confidentiality rules, meaning that it was unable to publicly defend its initial decision. It was only after the public summary document was released (four months after the PBAC meeting) that it became apparent that its decision was based on inadequate cost effectiveness, amongst other things. The initial rejection on cost effectiveness grounds and its subsequent listing at the lower price indicates that the product was initially judged to be overpriced. It also provides evidence that the results of cost effectiveness analyses do play a role in determining the actual price paid for vaccines

since the company offered a revised price that had more chance of making the vaccine cost effective on the resubmission.

The importance of cost-effectiveness in PBS recommendations is attested to in an earlier study by George et al. (2001) which, based on data from 355 submissions to the PBAC between January 1991 and June 1996, found there was a statistically significant difference between the cost per life-year gained for drugs that were recommended for listing and those that were not. While no explicit threshold for cost per life-year gained was found (i.e. a threshold beyond which the PBAC would unambiguously reject a drug for listing), the probability of listing was much higher for drugs with a cost per life-year gained less than Aus\$42,000 than for drugs with a cost per life-year gained greater than Aus\$76,000.

4. Strengths and Weaknesses of the Australian Approach to Cost Benefit Analysis of Vaccines

- The use of economic evaluation to determine whether a vaccine is listed should encourage allocative efficiency.
- The way in which the outcomes of economic evaluation are used for pricing and reimbursement, and the ability to resubmit rapidly following a negative PBAC recommendation, might in effect create a target price for manufacturers. This might weaken the competition between manufacturers, particularly in view of the small numbers of companies active in most vaccine markets.
- The real annual discount rate of 5% used in the evaluation of vaccines is higher than that used in a number of other countries, including the UK. Some researchers argue that a reduction in the discount rate would increase the likelihood of a vaccine being deemed cost effective due to the long time spans over which the benefits of vaccination tend to arise (Beutels et al. 2008).
- Taking a societal perspective in economic evaluation, rather than the current narrow direct health care costs / patient health outcomes perspective, could have a considerable impact on the view of vaccines' cost effectiveness.
- The same body, PBAC, is now responsible for evaluating both vaccines and curative pharmaceutical products. This differs from the situation in the UK, where there seems to be widespread agreement that responsibility for vaccines and other health care technologies should be separate because of the peculiarly specialised nature of vaccines.

5. Pricing and Reimbursement of Vaccines in Australia

The focus here is on pricing and reimbursement of vaccines on the Australian National Immunisation Program, as determined by the DoHA, which covers the large majority of the vaccines market in Australia. But we also discuss, later in this chapter, pricing and reimbursement of the minority of vaccines that are covered under the Pharmaceutical Benefits Scheme. Vaccines under the National Immunisation Programme are wholly paid for by the Commonwealth Government. However, vaccines on the Pharmacy Benefits Scheme do have a delivered price to the patient, part of which the patient must pay as a fixed copayment, with the Medicare scheme reimbursing the remainder of the price.

Today, price is negotiated with manufacturers centrally by the DoHA for both the National Immunisation Program and the Pharmaceutical Benefits Scheme.

The Australian system of vaccines pricing and reimbursement for the National Immunisation Program changed in one important respect on 1st July 2009: the responsibility for procurement moved from the State governments to the national Government from that date. Prior to July 2009, Commonwealth funding of vaccines was distributed to the States as part of the Commonwealth/State Public Health Outcome Funding Agreements (PHOFAs). The specific component of the PHOFAs relating to vaccines was covered by the Australian Immunisation Agreement. The Commonwealth determined which vaccines were listed on the National Vaccines Schedule of the National Immunisation Program and hence were eligible for Commonwealth funding. The amount of funding provided to each State under the PHOFAs was determined according to the dosage schedule for each vaccine and the size of the eligible population with an allowance for wastage. States could then choose which vaccines listed on the National Vaccines Schedule they would purchase using the funds provided under the PHOFAs. Commonly, multiple competing vaccines were listed on the National Vaccines Schedule.

However, From the Commonwealth's perspective, the payment of block grants to States under the PHOFAs for vaccines did not contain sufficiently strong performance incentives to achieve immunisation targets. While there was a formal requirement that any PHOFA funds designated for vaccines that remained unspent must be returned to the Commonwealth, the enforcement of this proved to be arduous with the result that States often successfully argued to retain any unspent funds to reallocate to other purposes. The desire by the national Government to retain control of those funds is likely to have been an important motivation for the switch to centralised procurement of vaccines from July 2009.

5.1. National Immunisation Program prior to 1st July 2009

With the exception of influenza vaccine, which has been purchased by the Commonwealth Government under a national procurement arrangement since 2003, there was no national procurement of vaccines before July 2009.

The national procurement of influenza vaccine was subject to tender in 2003 with two five-year supply contracts being let for the years 2004-2008 inclusive. Market shares for the two successful tenderers were set at 65% and 35%, with unit prices of Aus\$10 and Aus\$8 per dose respectively (source: interviews). The contracts were extended for two years to cover 2009-2010. The Australian Government has now called for tenders for new contracts commencing in 2011.

With this exception, vaccines were, before July 2009, subject to State procurement with States having the flexibility to choose which brands of vaccines they would purchase from those listed on the National Vaccines Schedule.

Even prior to July 2009, however, the prices of vaccines were negotiated centrally. That is, advised by the PBAC's recommendation (taking the economic evaluation into account), the Minister for Health and Ageing would decide whether the vaccine should be provided under Medicare, and if so whether as part of the National Immunisation Program or as part of the Pharmaceutical Benefits Scheme. There is no prescribed timeline with which the Minister will make this final decision. The time frame has in practice been anything from weeks to years.

Once the decision had been taken to include a vaccine in either of those schemes, the PBPA would advise on the appropriate price and the DoHA would then negotiate the actual price with manufacturers. The individual States took that nationally negotiated price as fixed and given, but then would conduct their own procurement tendering exercises. Where there was more than one potential supplier of a type of vaccine, the States were free to choose which supplier or suppliers they would use (if they wanted to split their state market between more than one companies); i.e. there was no national direction about which company's vaccine to buy.

As the price was fixed nationally, the competition at State level was about non-price aspects of the contracts to supply vaccines. While all jurisdictions were guaranteed that they could purchase a vaccine at the nationally negotiated price, there were other features on which vaccine suppliers would compete, such as: provision by the manufacturer of funding of registries; or support for health promotion campaigns.

From a vaccine manufacturer's perspective, the arrangement prior to July 2009 meant that they had to compete for the market in each State separately. There was no single competition for the whole Australian market. This meant that companies faced a lower risk than they now do under the new centralised procurement system that the company would end up with no part of the market, but they also faced a lower chance of being able to win the entire national market. Unless a sole supplier, companies faced uncertainty as to whether, and to what extent, each State would opt to purchase their vaccine.

5.2. National Immunisation Program since 1st July 2009

The new arrangements since 1st July 2009 are based on the National Partnership Agreement on Essential Vaccines arising from discussions by the Council of Australian Governments (COAG 2009). Transitional arrangements are smoothing the change from the old financial system to the new, but the arrangements for procurement changed immediately.

Under the new arrangements, States will no longer conduct a tender but they will have input into the development of the national Request for Tender (RFT) and the evaluation of tenders received. It is envisaged that, while the Commonwealth will negotiate tenders, the tender development process will be a collaborative process with the States and the States will have input into the negotiation process.

Under the new arrangements, just as before, a national price will be negotiated with the supplying company by the Commonwealth Government. Where there is more than one supplying company, market share will also be negotiated on a national scale, although this is as yet untested. The determination of market shares by the Commonwealth is a new feature introduced under the 2009 National Partnership Agreement. Under the previous arrangements, States could select the supplier or suppliers of a vaccine. Market share was therefore not pre-determined but reflected the outcome of States' individual decisions regarding the particular brand of vaccine which they selected for use in their jurisdiction. It is possible that the approach to be adopted will be similar to that for the supply of influenza vaccine in the past where the Commonwealth tendered for the supply of this vaccine and entered into contracts with two suppliers, on grounds of increasing the security of supply. The market shares for the two influenza vaccine suppliers are 65% and 35% respectively.

Under the new arrangements the Commonwealth Government negotiates a price for vaccines delivered to State warehouses, i.e. the price includes delivery up to that point. The States are responsible for the costs of their warehouses and for onward distribution of vaccines from there.

The main points of difference between the post- and pre-July-2009 vaccine procurement arrangements, which are not fully resolved owing to the change being so recent, are as follows (source: interviews):

- The most significant point relates to the listing of competing products which differ in some respects, e.g. vaccines that protect against different serotypes including a different number of serotypes, and vaccines that may confer additional protection against other diseases. An example is provided by the HPV vaccines Gardasil and Cervarix. Gardasil is a quadravalent HPV vaccine offering protection against serotypes 6, 11, 16 and 18. Cervarix is a bivalent HPV vaccine offering protection against serotypes 16 and 18. Gardasil also has established efficacy against external genital lesions (warts, and vulval and vaginal dysplasias) in women. How will the market shares of these two vaccines be set, particularly when there is a price

differential between them? There are various possibilities, but it remains to be seen which will happen in practice:

- Will the Commonwealth sign up with more than one supplier and negotiate market share?
 - Or will market shares emerge from States' choices of supplier(s)?
 - Or will the Commonwealth sign for 100% of the market with a single supplier; and if it did would it be prepared to choose a clinically inferior vaccine if were offered at a sufficiently low price?
- States are concerned about surety of supply and tend to favour arrangements where two or more viable suppliers are available from which they can source vaccines. Vaccine supply is tenuous, and there have been occasions where a supplier has not been able to fill orders. Granting 100% market share to a supplier may put surety of supply at risk, but there is no reason to believe that the national Government will not accord this the same weight as the States did in the past.
 - A nationally negotiated price is common to both the previous and the new arrangements, so will there be any difference in the resulting price with one national tender? Scepticism was expressed that this would be the outcome, for a given level of surety of supply, although it is also argued that the PBAC/PBPA listing process does not generate sufficient competition on price and that the national tendering system can therefore be expected to achieve lower prices.
 - The new arrangements will potentially simplify the Commonwealth/State relations in vaccine funding and supply. The previous system was complex. States were funded based on a formula that took into account population size, age and sex composition, wastage and leakage. Funds were provided prospectively, and as already explained this led to disputes between national and State governments about whether all the funds had been spent on vaccines. States will continue to distribute vaccines and support the National Immunisation Program as they have done in the past but they will no longer be provided with block grants based on projected vaccination coverage. Rather, they will provide the Commonwealth with quarterly forward estimates of expenditures on vaccines for approval by the Commonwealth but, if these funds are not actually spent on vaccines, they will not be covered by the Commonwealth. This is designed to remove the retention of unspent funds by the States as occurred under the old arrangements. States will also receive 'reward payments' for achieving specified coverage/disease targets (e.g. a coverage target for Aboriginal and Torres Strait Islander (ATSI) people).

5.3. Vaccines in the Pharmaceutical Benefits Scheme

The DoHA, advised by the PBPA, negotiates with manufacturers a single national price for each medicine and vaccine offered to residents of Australia under the Pharmaceutical Benefits Scheme. The focus of the PBPA is the ex-manufacturer (“wholesale”) price.

Companies have the option of seeking listing for their vaccine (or medicine) by either:

- pricing at or below the price of competing vaccines and submitting a cost-minimisation analysis to PBAC to justify that (in this case claiming no clinical superiority of their vaccine in relation to comparator products);
- or, if they seek a price higher than that of the comparator product, then they must submit a cost-effectiveness analysis to PBAC (in this case claiming clinical superiority of their vaccine in relation to comparator products).

In the latter case, based on a cost-effectiveness analysis, an additional step is involved, with the PBPA requiring an official statement by the company of the “cost of landed goods”, i.e. the cost of manufacturing or importing. To this is added a mark-up, which varies on a case by case basis but we understand is generally around 30%, though it can be lower for high volume products, to arrive at the ex-manufacturer price to be adopted as the basis of the listed price.

The ex-manufacturer price is augmented with a wholesale mark-up, a pharmacist mark-up and a dispensing fee to arrive at the “dispensed price” shown in the Schedule of Pharmaceutical Benefits. The patient then pays the first Aus\$33.30 of that price as a copayment, or Aus\$5.40 if they are entitled to a concession (e.g. because aged 65+), with Medicare reimbursing the balance.

The wholesale mark-up on the ex-manufacturer price is the amount added to the ex-manufacturer price that the wholesaler applies to the ex-manufacturer price as the fee for supplying pharmaceuticals to pharmacists. Currently, the wholesalers’ mark-up in Australia is set at 7.52% of the ex-manufacturer price (=7.0% of the ex-manufacturer + wholesale mark-up price) for ex-manufacturer prices up to and including Aus\$930.06 and is a flat Aus\$69.94 for ex-manufacturer prices over Aus\$930.06, which presumably excludes all vaccines (The Pharmacy Guild of Australia 2007).

The pharmacy mark-up varies according to the “approved price to pharmacist”, which is the sum of the ex-manufacturer price and the wholesaler mark-up, as set out in Figure 2, which is reproduced from The Pharmacy Guild of Australia 2007 (clause 14.4).

The final element of the public price of a vaccine under the Pharmaceutical Benefits Scheme is the dispensing fee, which currently stands at Aus\$5.99 (Source: Attachment E to PBPA 2009).

Figure 2: Pharmacy Mark-up on all Pharmaceutical Benefit Scheme Items, from 1 August 2008

<i>Pharmacy Mark-up^o</i>	<i>Mark-up on Approved Price to Pharmacist^o</i>	<i>Date of Effect</i>	<i>Value</i>
	<i>Up to and including \$30.00</i>	<i>1 August 2008</i>	<i>15%</i>
	<i>Between \$30.01 and \$45.00</i>		<i>\$4.50</i>
	<i>Between \$45.01 and \$180.00</i>		<i>10%</i>
	<i>Between \$180.01 and \$450.00</i>		<i>\$18.00</i>
	<i>Between \$450.01 and \$1750.00</i>		<i>4%</i>
	<i>Over \$1750.00</i>		<i>\$70.00</i>

Note: Approved price to pharmacist = ex-manufacturer price + 7.52% mark-up

6. Approach to Achieving Economic and High Quality Vaccines Supply

The approach to determining the vaccines provided under Medicare on either the National Immunisation Program or the Pharmaceutical Benefits Scheme, has already been described in detail. Medicare only funds vaccines deemed cost-effective by the PBAC, and all vaccines are, since July 2009, procured centrally by the DoHA. In this section we discuss the Australian approach to ensuring security of vaccines supply, to avoiding waste of vaccines, to the distribution of vaccines, and to encouraging the maintenance of a pipeline of new vaccines in future.

6.1. Security of supply and avoidance of waste

A major consideration in running the national immunisation programme is to ensure that the desired vaccines are available in sufficient quantities as and when required, while avoiding wasteful over-purchasing resulting in unnecessary levels of cold storage costs and eventual destruction of out-of-date stock.

Ensuring security of supply is adversely affected by two factors:

- vaccines are biological products, not chemicals, and they must in effect be grown, rather than manufactured. Thus if a manufacturer encounters a problem at a vaccine production plant – e.g. contamination – it takes time for alternative sources to expand production to meet the shortfall: months rather than days (House of Commons Committee of Public Accounts 2004, page 12, paragraph 21);
- small numbers of manufacturers of most vaccines.

Where different companies' vaccines are interchangeable the option exists to contract with two or more manufacturers at a time in the interests of greater security of supply: typically giving the larger share of the contract to the lower cost bidder but giving a substantial minority of the market to another supplier. We understand from our interviews that this option has in the past been taken up by State governments when procuring vaccines pre-July-2009, and by the national DoHA when procuring influenza vaccine. The latter suggests that the complete centralisation at the national level of vaccines procurement since July 2009 will not hinder the continued use of more than one supplier where possible.

However, it is early days yet for the new arrangements and we are not aware of any decisions being made about how a multi-supplier national contract would be applied to each of the States. Would each State be free to choose how much it took from each supplier? If so, that would only by chance if at all coincide with the split of the market negotiated by the DoHA with the respective vaccine manufacturers. Conversely, we have not heard of any arrangements yet being

established whereby the DoHA could direct a State government to take vaccine manufactured by one company when they wish to take the vaccine manufactured by the other company with a national contract. This part of the new vaccine procurement arrangements is, therefore, currently unclear.

One of the vaccine company interviewees expressed some concern that the Commonwealth DoHA will be subsuming a number of functions previously performed by the States and may have underestimated the difficulties associated with this. Under the pre-July-2009 system, GPs and local councils would lodge an order for vaccines with the Department of Health in their particular State. The State health department would scrutinise the order and, if approved, would arrange for the delivery of the requested vaccines from the State warehouse. An advantage of this arrangement was that it gave the State governments considerable control over vaccine supply and enabled them to avoid wastage arising from excess orders. The exercise of this control function requires a considerable degree of local knowledge which the Commonwealth does not possess, not yet anyway. Will GPs and local councils order their vaccines from Canberra in the future? Or will they still order from the State government who will then in turn have to transmit the order to Canberra? This is not yet known, but if they do then the control function will be more difficult to manage.

6.2. Distribution

Vaccines included in the National Immunisation Programme are paid for on the basis of a price delivered to State warehouses. Thus vaccine companies absorb the costs of delivery to those warehouses and take responsibility for arranging and paying for distribution. Vaccines on the Pharmaceutical Benefits Scheme are sold by manufacturers both by direct supply and through wholesalers.

Our interviewees reported that CSL Logistics is the company that dominates the vaccines distribution market in every Australian State. It provides delivery services both from manufacturers to State warehouses and, on behalf of State governments, from State warehouses to GPs and local clinics.

State governments usually only contract with one supplier to deliver from their warehouses to GPs and clinics, and in practice this is usually CSL Logistics.

6.3. Dynamic efficiency: maintaining the flow of new vaccines

The problems of maintaining, globally, a research pipeline producing new and improved vaccines are well documented in the economic literature and apply across all countries (see for example: Danzon et al. 2005; Offit 2005; and Stephenne and Danzon 2008). In essence they arise from the fact that research development and testing of vaccines, and the manufacture of them, involved

high fixed and sunk costs relative to the scale of the potential market; and that the demand for vaccines tends to be concentrated in the hands of a small number of (public) organisations.

Centralised government contracting can be seen by vaccine manufacturers as a disincentive for innovation and new technology when (low) pricing is seen to be the dominant criterion for tender award, as there is then little encouragement for developing higher quality vaccines if they are going to cost more.

One of our vaccine company interviewees in Australia saw the newly centralised arrangements as embodying a number of risks for them:

- while market share will be negotiated with the Commonwealth, it is not clear how the agreed market shares will be achieved in practice when more than one supplier is contracted nationally, as States will apparently retain the ability to choose which brands of vaccine are used in their programmes;
- thus, in that situation, the national procurement negotiations will bind successful tenderers to supply if required but without a viable market share guarantee; and
- while State governments and the national government may regard dual supply as achieving surety of supply, companies may face considerable uncertainty as to market share, and hence supply requirements, unless they have 100% of the market.

There is recognition by government of the need to preserve responsiveness to the arrival of new vaccines and to avoid “locking out” competitors. One mechanism to achieve this may be through different terms of contract (e.g. 2 years, 4 years) depending upon whether new vaccines are known to be in the pipeline.

7. Strengths and Weaknesses of the Australian Approach to Pricing and Supply of Vaccines

The procurement of most vaccines in Australia is highly centralised in the national Government's Department of Health and Ageing. Before July 2009, the eight State governments undertook their own separate procurement exercises and could select their own preferred suppliers of vaccines as a result, where more than one supplier was in the market. In so doing they were able to obtain additional benefits from vaccine companies such as contributions to health promotion and other programmes. But even then:

- the selection of vaccines for inclusion in the National Immunisation Programme was undertaken centrally – by the DoHA, advised by the PBAC and ATAGI; and
- the price was negotiated and fixed centrally by the DoHA, advised by the PBPA.

The relatively small number of vaccines covered by the Medicare Pharmaceutical Benefits Scheme have also long had their reimbursement prices fixed by national negotiation; and influenza vaccine has been centrally purchased since 2003.

Thus it is arguable that for most purposes the Australian vaccines market has been characterised by a high degree of centralisation of procurement for many years.

We found no particular resistance to centralisation per se from any of our interviewees, whether at companies, State governments or national government levels. But given the newness of the post-July-2009 arrangements there is uncertainty and consequently nervousness about how they will work out in practice.

The main advantages of centralised purchasing are in principle:

- economies of scale. A centralised buyer has the greatest possible market power. This is further enhanced by the DoHA being responsible also for immunisation policy in Australia, and for designing policies to encourage high rates of uptake of vaccines. Thus the DoHA is able to deliver not only the whole Australian market for a vaccine, but also to demonstrate that it has policies in place to help maximise that market. Centralisation should therefore enable the greatest scope for volume-related economies and related price discounts to be realised. The potential downside is that manufacturers may exit the market if they fear a significant risk of winning none of it because there is a single 'all or nothing' tender. DoHA can mitigate this by sometimes splitting the national market between two, or even three, manufacturers;
- greater influence over manufacturers. The influence is derived as described in the preceding bullet point. This influence can be used not only to improve the terms under which vaccines are obtained, but also to encourage manufacturers to, for example, conduct clinical trials of their vaccines and other products in Australia, and to launch them in the Australia earlier rather than later, which helps to improve access to new vaccines (and other products) for Australia.

On the plus side, centralisation was seen as reducing the administrative costs of the scheme: only one national procurement exercise to go through each time rather than a national price negotiation plus eight State procurement exercises. The downside from a company perspective is that centralised purchasing potentially increases the market risk – i.e. the greater risk of winning no part of the Australian market as compared with a decentralised approach with multiple buyers. But this is tempered by DoHA's already demonstrated willingness to sometimes award contracts to two or three suppliers rather than one, and because of the greater size of the market that the DoHA is able to deliver to the successful bidder in comparison with a State department of health.

The greater problem that might be posed by centralisation is in the longer term if manufacturers fear that R&D into new and improved vaccines will not be rewarded adequately, i.e. if they fear short-sighted opportunistic behaviour by a centralised purchaser unwilling to recognise and pay for the sunk costs of producing vaccines. Overcoming this problem depends on the centralised purchaser making credible undertakings to pay prices that reflect the total costs of cost-effective (at such prices) new vaccines. This problem may also be attenuated to a greater or lesser degree by the relatively small size of the Australian market in a global context.

The overall conclusion from the Australian case study appears to be that:

- centralised purchasing is long established in terms of price setting and so may be assumed to be viable at least in that respect; but
- it is still too early to gauge the net impact of the July 2009 move away from State level choice of supplier given a nationally fixed price, where more than one supplier is potentially available.

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