VALUE IN PHARMACEUTICAL PRICING

COUNTRY PROFILE: AUSTRALIA

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List of acronyms

ATC	Anatomical therapeutic chemical
CBA	Cost-benefit analysis
CEA	Cost-effectiveness analysis
DHA	Department of Health and Ageing, Australian Government
DUSC	Drug Utilisation Sub-Committee
ESC	Economics Sub-Committee
ICER	Incremental Cost-effectiveness Ratio
LSDP	Life Saving Drugs Program
PBPA	Pharmaceutical Benefits Pricing Authority
PBAC	Pharmaceutical Benefits Advisory Committee
PBS	Pharmaceutical Benefit Scheme
PSD	Public Summary Documents
TGA	Therapeutic Goods Administration

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Contextual information on pharmaceutical coverage and pricing

1. Australian residents are covered for health services by a national scheme (Medicare), which covers a number of programmes. One of these, the Pharmaceutical Benefit Scheme (PBS), assists with the costs of prescription medicines dispensed in the community and private hospitals and some pharmaceuticals dispensed to public hospital outpatients and in public hospital emergency departments.[1] In addition to the drugs and medicinal preparations listed in the general Schedule of PBS, the federal government also funds a number of drugs, which are distributed under alternative arrangements.[2] These are highly-specialised medicines and many cancer drugs. The programme defines maximum quantities and the number of repeats which can be funded. For some of these medicines, prior authorisation is required.

2. Patients contribute to the costs of medicines under the PBS through copayments (up to AUD 35.40 per prescription in 2012 for general patients). Holders of a Commonwealth Concession Card ("concessional patients", i.e. pensioners and veterans) are entitled to lower copayments (AUD 5.80).[3] Access to a Concession card is means tested.

3. Australia uses reference pricing for generic clusters and for groups of drugs with similar safety and health outcomes that can be used interchangeably (therapeutic groups). The maximum reimbursement amount for a medicine in a therapeutic group is based at the level of the lowest price in the group and patients pay any difference between the price of the drug purchased and the reference price. If a patient cannot take a medicine in the same therapeutic group, due to a clinical reason certified by the doctor, the government will pay the premium contribution on his/her behalf.

1. The responsibility for providing pharmaceuticals to public hospital inpatients lies with state and territory health departments. Residents of all states, except New South Wales and the Australian Capital Territory, are eligible to PBS access when attending public hospital outpatient and emergency departments.

2. These alternative arrangements are provided for under section 100 of the National Health Act 1953 and often referred to as "section 100" listing by opposition to other products of the general PBS schedule (section 85 of the same act). See www.pbs.gov.au/browse/section100, for the list of medicines. Among the medicines selected for the OECD study boceprevir (for Hepatitis C) is included in "section 100" list.

3. www.pbs.gov.au/info/about-the-pbs.

4. The Therapeutic Goods Administration (TGA), a division of the Australian Government Department of Health and Ageing (DHA), grants marketing authorisations. Manufacturers of prescription medicines have to file an application to the Pharmaceutical Benefits Advisory Committee (PBAC) for their medicine to be subsidised under the PBS. The PBAC must assess whether the medicine is both clinically effective and cost-effective (compared to other treatments) before recommending that a product should be added to the Pharmaceutical Benefits Scheme (PBS). In practice, most prescription drugs are included in this list.

5. Once the PBAC has issued a positive recommendation for inclusion in the PBS, the government may seek to regulate its reimbursement price.

6. Since 2006, drugs covered by the PBS are listed in two formularies (DHA, 2010):

- Formulary One (F1) consists of drugs which have only one brand each;
- Formulary Two (F2) consists of drugs which have two or more brands each.

Drugs on F1 move to F2 when the first additional brand is listed on the PBS.

7. On a macro-level, PBS expenditure is not capped in Australia. However, pharmaceutical prices can be reduced.

Pricing and reimbursement: decision making process

8. According to the DHA, the core objectives of Australia's National Medicines Policy are the following (Department of Health and Ageing, 2010):

- Timely access to medicines Australians need, at a cost individuals and the community can afford;
- Medicines that meet appropriate standards of quality, safety and efficacy;
- Quality use of medicines;
- Maintaining a responsible and viable pharmaceutical industry.

9. Manufacturers of prescription medicines have to file an application to the Pharmaceutical Benefits Advisory Committee (PBAC) for their medicine to be subsidised under the PBS. The PBAC considers an economic evaluation, at the price initially set by the manufacturer, to determine whether the product should be included in the PBS list.

10. Once the PBAC has issued a positive recommendation, the PBS listing of the drug must be considered by the government. The Minister for Health is the ultimate decision maker for PBS listing after the positive recommendation from the PBAC. In particular circumstances, such as when the proposed drug and its comparator produce similar clinical results, the PBAC may recommend a lower price than the price proposed by the manufacturer, on the basis of the results of the economic evaluation. In such case, the PBAC recommendation is followed by negotiations on price.

Assessment phase for reimbursement decisions

Institutions, experts and stakeholders

11. The Pharmaceutical Benefits Advisory Committee (PBAC) is responsible for the assessment of manufacturers' submissions for listing of new drugs or substantial changes in listing conditions of drugs already listed. The PBAC has established two sub-committees:[4]

- The Economics Sub-Committee (ESC) advises on cost-effectiveness policies and evaluates cost-effectiveness aspects of major submissions to the PBAC. The ESC includes 12 experts in health economics or clinical fields (public health, pharmacy, epidemiology and other specialties) and one pharmaceutical industry representative.

- The Drug Utilization Sub-Committee (DUSC) monitors the patterns and trends of drug use and makes utilization data available publicly. The DUSC includes nine qualified experts, a consumer and two industry representatives.

12. The Pharmaceutical Benefits Advisory Committee (PBAC) is an independent statutory committee, which meets three times per year. It is assisted by a secretariat and contracted teams of expert academic evaluators. As an independent Committee, the PBAC determines its own decision-making process in closed sessions. Only members of the Committee can participate in the decision-making process. PBAC members are usually appointed for a period of four years by the Minister for Health. Members are medical practitioners (specialists, general practitioners and clinical pharmacologists), pharmacists, consumers and health economists. There is no pharmaceutical industry representative on the PBAC.

Assessment principles

13. The PBAC has edited Guidelines for preparing submissions[5] to the Pharmaceutical Benefits Advisory Committee whose aim is to provide practical information (including guidance for economic evaluations) to the pharmaceutical industry for making a submission to PBAC and to help PBAC assess submissions.

14. The assessment of drugs for inclusion in the PBS lists is based on a pharmacoeconomic evaluation from a healthcare system perspective. The PBAC prefers to operate on an incremental cost per extra QALY gained basis. Value is assessed when PBAC compares the cost and benefits of a new drug with those of an existing therapy to calculate its incremental cost-effectiveness ratio (ICER).

15. The PBAC applies the same rules to all medicines in all therapeutic areas. The committee considers a range of relevant factors in addition to incremental cost-effectiveness (Chalkidou et al., 2012):

- Clinical need, particularly for conditions for which there are no, or few, treatment options;

- The extent to which a proposed treatment represents a clinically meaningful advance in therapy;

- The degree of uncertainty in the estimate of incremental cost-effectiveness;

4. www.pbs.gov.au/info/industry/listing/participants/pbac

5. Guidelines for preparing submissions to the PBAC – December 2008 can be found here: www.health.gov.au/internet/main/publishing.nsf/Content/pbacguidelines-index

- The potential total cost to the PBS or government health budgets;
- The scope for use of the drug beyond any restriction for subsidy, and the extent to which a restriction can be constructed that satisfactorily distinguishes use that is acceptably cost-effective from use that is not cost-effective;
- The potential for adverse outcomes arising from availability with subsidy (e.g., the PBAC may restrict subsidized use of certain antibiotics to limit the development of resistant organisms);
- The affordability of the medicine to the patient in the absence of a subsidy;
- The "rule of rescue" – reserved for drugs for serious or fatal diseases for which no other treatment is available.

Submission requirements

16. The PBAC distinguishes three types of submissions, with different requirements in terms of information (PBAC, 2008):[6]

- *Major submissions* must include an economic evaluation, according to guidelines published by the PBAC. Major submissions are needed in the following cases: listing of a new drug (i.e. a new fixed combination product, a new nutritional product, a new vaccine, or a new orphan drug); substantial change in a "restricted listing" (e.g. listing for a new indication or lifting of restrictions); request for a review of the comparative cost-effectiveness of a currently listed drug in order to change a PBAC recommendation or obtain a price advantage; listing a new form or strength of a currently listed drug for which a price advantage is requested.
- *Minor submissions* do not usually require the submission of an economic evaluation. They relate to new forms of previously listed products (with no price advantage sought and small expected impact on volumes) or changes to the conditions of use (e.g. change in maximum quantity per prescription or maximum number of refills).
- *Submissions to list generic equivalents* are assessed by the DHA and usually do not need to be assessed by the PBAC.

17. When considering orphan drugs, PBAC does not set a minimum standard for the type and level of evidence or other information that can be included in a submission to the committee. Nonetheless, the PBAC is required to consider comparative costs and effectiveness.

Types of economic evaluation

18. An economic evaluation is required for all major submissions. However, PBAC requirements differ according to additional benefits of the new medicine over its competitors. PBAC Guidelines indicate which type of evaluation is needed in each case (PBAC, 2008). Cost-utility analysis is generally preferred when the proposed drug is therapeutically superior to the main comparator.

6. See also : www.pbs.gov.au/info/industry/listing/elements/pbac-guidelines/a-part-1/section-3, consulted on January 31, 2012.

Table 1. Link between therapeutic benefits of the new product and the type of economic assessment considered by PBAC

Comparative safety	Comparative effectiveness			
	Inferior	**Uncertain**	**Non-inferior**	**Superior**
Inferior	Health forgone: need other supportive factors	Health forgone possible need other supportive factors	Health forgone: need other supportive factors	? Likely CUA
Uncertain[a]	Health forgone possible: need other supportive factors	?	?	? Likely CEA/ CUA
Non-inferior[b]	Health forgone: need other supportive factors	?	CMA	CEA/ CUA
Superior	? Likely CUA	? Likely CEA/ CUA	CEA/ CUA	CEA/ CUA

CEA = cost-effectiveness analysis; CUA = cost-utility analysis; CMA = cost-minimisation analysis.
? = reflect uncertainties and any identified health trade-offs in the economic evaluation, as a minimum in a cost-consequences analysis.
a) "Uncertainty" covers concepts such as inadequate minimisation of important sources of bias, lack of statistical significance in an underpowered trial, detecting clinically unimportant therapeutic differences, inconsistent results across trials, and trade-offs within the comparative effectiveness and/or the comparative safety considerations (e.g. where the toxicity profiles of the compared drugs differ, with some aspects worse for the proposed drug and some aspects better for the proposed drug).
b) An adequate assessment of "non-inferiority" is the preferred basis for demonstrating equivalence.

Source: Pharmaceutical Benefits Advisory Committee Guidelines (2013).

Criteria for clinical assessment: health outcomes

19. PBAC considers end-point outcomes, such as deaths prevented, life-years gained, or quality-adjusted life-years gained. Surrogate outcomes are accepted when final outcome data are not available, and where the model used in the analysis shows a link between surrogate and final outcomes (PBAC Guidelines, 2008).[7]

Choice of comparators for comparative effectiveness analysis

20. Pharmaceutical companies are expected to identify "the main comparator" in their submissions to the PBAC, defined as "the therapy that prescribers would most replace with the proposed drug in practice if the PBS subsidises the proposed drug as requested". The 2008 guidelines include details on the method to identify the main comparator (PBAC, 2008), which are summarised below.

21. In practice, the main comparator can be difficult to identify. In some cases, comparisons with more than one comparator will be necessary. The following rules aim to assist applicants in selecting the appropriate comparator and sponsors can always seek advice from the PBAC Secretariat and/or the Pharmaceutical Evaluation Section:

- If pharmacological analogues are already listed, the main comparator will usually be the most prescribed one, unless important differences exist in the set of indications. If important differences exist in the set of indications, the main comparator is the drug most prescribed to treat the proposed indication for the proposed drug.

7. www.health.gov.au/internet/main/publishing.nsf/Content/pbacguidelines-index, consulted on January 15th, 2012.

- If the proposed drug is in a new therapeutic class but will be used for an indication for which there are other drugs widely used to treat that indication, the main comparator will usually be the drug which is the most prescribed to treat that indication.

- If no currently listed drug is available, the main comparator will usually be standard medical treatment (this could include a surgical procedure or conservative management). This should be clearly and consistently defined in both the submission and the comparative randomised trials.

22. If the drug is supplied in a special formulation (e.g. sustained release tablets, oral pressurised inhalation), the main comparator selected according to the above criteria should be in a similar formulation, if available.

23. Prescribing practice can change rapidly and a drug chosen on reasonable grounds at the outset as the main comparator may not always be so relevant at the time of submission. This is particularly likely given the long time necessary to obtain primary data as part of Phase III or Phase IIIb trials. Allowance will be made for this during the evaluation of submissions. If a sponsor is designing such a trial with a view to eventual submission to the PBAC, the advice of the PBAC Secretariat and/or the Pharmaceutical Evaluation Section may be sought. No guarantee can be given that the PBAC will be constrained by this advice when considering the eventual submission, as important factors could change, such as a different approved indication to that originally anticipated. A submission incorporating a trial based on this advice will be accepted for evaluation, but it may be necessary to present an analysis based on two sets of randomised trials involving the originally chosen comparator as a common reference.

24. If the only comparative randomised trials available use a comparator that is different to the main comparator chosen according to PBAC guidelines (for example, these may be trials conducted overseas where the appropriate comparator is different), it may also be necessary to present an analysis based on two sets of randomised trials involving the overseas comparator as a common reference.[8]

Assessments of costs

25. The categories of costs considered by PBAC are the following (PBAC, 2013)[9]:

- *Direct health care resources***:** (a) drugs (direct costs of treatment and of drugs used to treat side effects); (b) medical services including procedures; (c) hospital services; (d) diagnostic and investigational services; (e) community-based services; and (f) any other direct medical costs.

- *Direct non-health care resources:* such as social services (home help, day care, meals on wheels, nursing and physiotherapy services etc.) may be relevant only on special occasion, e.g. particular condition under treatment or the age of the patients. Some of these are included in the *Manual of Resource Items and their Associated Costs.*

- *Natural units of direct health care resources:* Define the natural units (such as number of GP consultations or admissions per DRG) used to measure the change in the amount of resources provided (see also the *Manual of Resource Items and their Associated Costs)*

8. Section B(i), Part III of PBAC (2008) gives further advice on presenting such an indirect comparison.

9. Section D.4, Part II and Appendix 9 of PBAC (2013) give further advice on variables to be considered in economic evaluations.

- *Indirect economic outcomes:* These include potential working time gained or lost measured in time units (days, weeks, years etc). They may also include potential impaired working time gained or lost by sick patients continuing to work measured in similar time units together with a measure of the extent of impairment. Particular care is needed when considering indirect economic outcomes when using surrogate outcome indicators (their combination may be inappropriate) or utilities (to avoid double-counting the estimates of benefit, see also Appendix 9 of the 2013 PBAC Guidelines).

Implicit or explicit cost-effectiveness threshold

26. PBAC guidelines do not explicitly specify a threshold under which an incremental cost-effectiveness ratio (ICER) is considered attractive. Although PBAC does not appear to work with an explicit threshold value, a study reports that observation of the decisions of the PBAC between 1994 and 2003 pointed to an apparent threshold of AUD 69 900 per QALY gained, above which reimbursement was found to be unlikely (Henry, 2005). A more recent study analysed the outcome of the assessment of submissions to the PBAC for product-indication between July 2005 and November 2009: about 59% of these received a positive recommendation for listing (with or without restrictions) and 41% of decisions were "deferred" or negative. Among assessments including an ICER value (about 50% of all assessments), the percentage of positive recommendations decreased when the ICER increased: 51% of submissions with an ICER inferior to AUD 45 000 were accepted, against 33% when the ICER was in the AUD 45 000-75 000 range and 16% beyond AUD 75 000 (Mauskopf et al., 2013). There is however no evidence that this implicit threshold is effectively used to guide PBAC's decisions (Cleemput et al., 2008). Hence, each application is considered by the PBAC on its merit, with the acceptability of each incremental cost-effectiveness ratio considered on a case-by-case basis.

27. PBAC assessment reports do not include the exact value of the ICER of the drug evaluated but only indicate the range in which the ICER of the product (for a specific indication) is included: AUD 15 000 to 45 000; 45 000 to 75 000; 75 000 to 105 000; 105 000 to 200 000. In the sample of products considered in this study, medicines with ICER higher than AUS 75 000 were never recommended for inclusion in the PBS schedule, and medicines (or indications) with an ICER higher than AUS 45 000 were recommended only in exceptional circumstances (high clinical need and no alternative).

Consideration of end-of-life treatments

28. The PBAC applies similar rules to all medicines with no special treatment for oncology or other "end-of-life" medicine. However, the PBAC takes into account the "rule of rescue" factor for each drug submission. This is applied rarely and only for medicines for life-threatening condition for which there is no other effective treatment available in Australia, either subsidised or unsubsidised (Chalkidou et al., 2012).

29. The Life Saving Drugs Program (LSDP) provides subsidised access for eligible patients to expensive life saving drugs for very rare life-threatening conditions where the drugs are not recommended for inclusion on the PBS. Before a drug is made available on the LSDP it must be assessed by the PBAC as clinically necessary and effective, but not recommended for inclusion on the PBS due to unacceptable cost-effectiveness. During 2010-11, nine drugs were funded through the programme for the treatment of 210 patients with seven different disorders.[10] Each condition has separate eligibility guidelines, developed

10. Drugs funded through the LSDP in 2013 included the following: imiglucerase (Cerezyme®) and miglustat (Zavesca®) to treat Gaucher disease; agalsidase alfa (Replagal®) and algalsidase beta (Fabrazyme®) for Fabry disease; laronidase (Aldurazyme®) for Mucopolysaccharidosis (MPS) Type I; idursulfase (Elaprase®) for MPS Type II; galsulfase (Naglazyme®) for MPS Type VI; alglucosidase alfa

and administered with the advice of an expert disease advisory committee, and any amendments are submitted to the PBAC for consideration (DHA annual report 2010-2011).

Consideration of orphan drugs

30. The PBS provides specific funding for patients treated in public hospitals for certain high cost drugs but there is no special explicit consideration of orphan drugs, apart from the Life Saving Drugs Program, which operates outside the PBS and funds a small number of "ultra orphans" (see above).

Outcome of the process

31. In 2009-10, PBAC considered 216 submissions, of which 73 were major submissions requiring cost-effectiveness analysis, and 143 were minor submissions which did not require a cost-effectiveness analysis. In 2010-11, PBAC considered 191 submissions, of which 63 were major submissions and 128 minor submissions (DHA Annual Report 2010-2011).

32. PBAC recommendations are provided to product sponsors and the Minister for Health and are publicly available through "PBAC Outcomes" (published around 8 weeks after a PBAC meeting). Public Summary Documents (PSDs) are published around 4 months after the relevant PBAC meeting. The PSD includes information on the economic analysis presented by the company and PBAC evaluation of the cost effectiveness claims, as well as PBAC recommendation and reasons.[11]

33. PBAC recommendations are valid for a period of five years. If the PBAC does not make a recommendation to list, the applicant may re-submit with new or additional information at any time.

Pricing policy

Who sets the price of a new drug?

34. Pharmaceutical companies set the price of their drug in the non-PBS market without regulatory intervention. Where listing on the PBS is sought, the PBAC is responsible for the assessment of the proposed price for listing and can deny inclusion on the list until the company reduces the price or impose restrictions in use to a particular patient sub-group likely to benefit most from the drug. This process is an incentive for manufacturers to adjust prices in order to receive a positive PBAC recommendation.

35. In addition, the government and the manufacturer must formally agree on the price of a product before listing on the PBS, and, in the cases of drugs subject to a risk-sharing arrangement, the terms of conditions in any such arrangement. The government cannot compel a manufacturer to list a product on the PBS.

Institutions and stakeholders

36. The Pharmaceutical Benefits Pricing Authority (PBPA) is a non-statutory committee that meets three times a year following PBAC meetings to help the government negotiate the final price at which a drug should be listed on the PBS. It may recommend either a ceiling price or price range for an item that has been approved by the PBAC following negotiation. The PBPA is supported by a secretariat which operates within the DHA.

(Myozyme®) for infantile-onset pompe disease; and eculizumab (Soliris®) for Paroxysmal Nocturnal Haemoglobinuria. Updated information on the LSDP is available at http://www.health.gov.au/lsdp.

11. www.health.gov.au/internet/main/publishing.nsf/Content/public-summary-documents-by-product.

37. The Pharmaceutical Benefits Pricing Authority includes representatives from the pharmaceutical industry (R&D based and generic), from consumers, from the Department of Health and Ageing and from the department of Innovation, Industry, Science and Research.

How are prices set?

38. The PBPA reviews prices of listed drugs and recommends prices for new drugs which have been recommended by the PBAC for listing. When considering prices, the PBPA may consider a range of factors (PBPA, 2011; DHA, 2013):

- PBAC comments on clinical and cost-effectiveness aspects of items;
- The prices of alternative brands of a drug;
- Comparative prices of items containing drugs in the same ATC group;
- Cost information provided by the drug supplier or estimated by the PBPA;
- Prescription volumes, economies of scale and other factors such as expiry dates, storage requirements, product stability and special manufacturing requirements;
- Prices of items containing the drug in reasonably comparable overseas countries;
- Other relevant factors which the applicant company may wish the PBPA to consider;
- Any directions of the Minister of Health.

39. The level of activity being undertaken by the company in Australia, including new investment, production, research and development" was explicitly taken into account in the past but is no longer considered (PBPA, 2010).

Pricing methods

40. The PBPA uses the following methods to recommend prices (PBPA, 2009):

- The *Cost Plus method* consists in granting a gross margin on the costs of manufacturing. This margin is set on a case by case basis. A 30% margin is usually considered reasonable, but higher margins may be recommended for low-volume products (particularly those with a cost to the PBS of AUD 50 000 per annum or less) and lower ones may be recommended for high-volume products.
- *Reference prices* (for clusters of therapeutically similar products) are set according to the principle of cost-minimisation. The lowest-priced medicine sets a benchmark price for other drugs of the cluster.
- The *Weighted Average Monthly Treatment Cost (WAMTC)* methodology is a particular type of reference pricing, aiming to adjust the prices of drugs providing similar health outcomes so that the monthly treatment cost is not statistically significantly different. This method is currently applied only to those drugs which are included in Therapeutic Groups (five classes of drugs: H2 receptor antagonists, angiotensin-converting enzyme inhibitors, angiotensin II receptor antagonists, proton pump inhibitors and higher-potency statins group comprising atorvastatin and rosuvastatin).

41. Where a medicine has more than one indication and a cost-effectiveness that varies across indications, a weighted average price according to expected volumes of use across the indications is set.

Risk-sharing agreements

42. Risk-sharing agreements are increasingly used to contain overall costs of drugs included in the PBS or to manage financial risks for the government. At 30 June 2013, there were 76 agreements in place or in development (DHA, 2013). Risk-sharing agreements are made on a commercial and confidential basis and are not publicly available.

43. Several types of risk-sharing schemes are employed in Australia (Pugatch, 2010):

- Price volume agreements (PVAs) are used for individual medicines or a group of medicines treating a certain disease. In these agreements, any excess in the forecasted budget will lead to price reductions or rebates (% of costs) paid to the government by the company. Some schemes impose rebates on costs generated by uses outside of the restrictions set by the PBAC. Other schemes use a combination of both.

- Some agreements take the form of performance-based agreements.

44. The funding of medicines, including those subject to risk-sharing agreements, may restricted, in accordance with PBAC recommendations, for instance "to patients with severe cases of the disease, who have failed to adequately respond to cheaper or less toxic existing therapies". In some cases, patients must formally agree that their access to a new treatment will only continue if it produces an adequate response, according to predetermined criteria.

Consideration of budget impact

45. The Department of Health and Ageing (DHA) administers the Pharmaceutical Benefit Scheme. Decisions are made on the basis of cost-effectiveness and budget provision must be made by the government in its forward estimates before drugs are included on the Schedule.

46. Until recently, when the budget impact of a single drug was expected to exceed AUD 10 million per year, its inclusion in the PBS required approval from the Cabinet. This could be drugs with low cost and high use or drugs with low utilisation but very high costs (Lu, 2008). Given the current fiscal environment, the government decided in 2010-11 that all positive recommendations made by the PBAC and the PBPA for new or amended PBS listings and price increases which have a financial impact for the government, will be considered by the Cabinet (DHA, 2011).

Price changes

47. The price of each drug listed in the PBS is reviewed annually by ATC groupings. Manufacturers are asked to submit cost and other data that they wish to be considered in reviewing product prices.

48. Drugs included in the PBS list can be subject to several types of price reductions.

- Since 2007, the first time a new brand of a currently listed drug is listed on the PBS, the price of all brands of that drug is reduced by 12.5 per cent. This statutory reduction increased to 16 percent from 1 April 2011 for all new first time listings of a new brand of an existing PBS listed medicine.

- Additional statutory price reductions of 2% and 5% occurred on 1 February 2011 for all non-exempted medicines on the F2 formulary.

- A policy of price disclosure has been progressively implemented since 2007 for drugs in F2. Manufacturers are required to provide information on the actual selling price of their drugs to the Department of Health and Ageing (i.e. including rebates and incentives to wholesalers and pharmacies). With this information, the DHA computes the "weighted average disclosed price" (WADP) to reflect the price at which the drug is being supplied in the market. If this WADP is more than 10 per cent below the PBS price, then the PBS price is reduced to the WADP.

Final decision making

Role of government

49. The Department of Health and Ageing (DHA) manages the Schedule of Pharmaceutical Benefits. The Medicare part of the Department of Human Services administers the operations of the PBS on behalf of the Australian Government. The DHA is responsible for maintaining the Schedule, including by listing new drugs following approval from the government which takes into account recommendations from the PBAC and the PBPA. The government may reject a positive recommendation from the PBAC, but this happens only rarely (Morgan et al., 2008). The minister cannot list a medicine without a positive PBAC recommendation.

50. As mentioned before, since 2011, the Cabinet needs to approve any new listing, or change to an existing listing.

Outcome of the process

51. Listing of a new drug in the PBS may be restricted to certain uses. Many medications on the PBS are subsidised for a specific patient group or indication. The DHA distinguishes three categories according to their degree of restriction (DHA website):

- Unrestricted benefits (with no restriction in the therapeutic use);

- Restricted benefits (the medicine can only be prescribed for specific therapeutic uses);

- And "authority required benefits" for which doctors need prior approval from Medicare in the Department of Human Services or the Department of Veterans' Affairs.

52. High-cost medicines are commonly subject to "prescription requirements" to control their use (Lu et al., 2008). For some high-cost drugs (e.g. trastuzumab, imatinib, and gefinitib), public funding requires confirmation that the patient is likely to respond, i.e. carries the specific genetic marker (Lu, 2008).

53. In 2011-2012, 142 new PBS medicines or extensions to existing PBS listed medicines were included in the positive list. In addition, one medicine was included on the Life Saving Drugs Program (LSDP). Due to a difficult fiscal environment, the listing of seven medicines was deferred for a few months. [12] The government did not include these drugs because therapeutic alternatives were available in the PBS (Doecke, 2011). All these drugs were finally listed at the end of 2011.

12. The seven deferred medicines were: dutasteride with tamsulosin hydrocholide (Duodart®), paliperidone palmitate (Invega Sustenna®), oxycodone/naloxone (Targin®), budesonide with eformoterol

54. In 2010-11, the PBS subsidised more than 760 medicines available in more than 1,960 forms and more than 3,950 differently branded items (DHA Annual Report 2010-2011).

Published decisions

55. The schedule, which lists all medicines available under the PBS, is available at www.pbs.gov.au. It is updated monthly to include new listings and the latest changes.

Contestability

56. An applicant can seek procedural review of a PBAC outcome through the judiciary. Independent review is also available where the PBAC did not make a recommendation to list; and in certain circumstances where the PBAC did not recommend the listing of an additional indication for an already-listed drug on the PBS.[13]

(Symbicort®), botulinum toxin type A (Botox®) extension, dalteparin sodium (Fragmin®), and nafarelin (Synarel®). One of these drug was later included in the PBS (Duodart®) in August 2011 (DHA annual report 2010-2011). The remaining six deferred medicines were all listed on the PBS on 1 December 2011.

13. Further information on the eligibility requirements for independent review is contained at: www.independentreviewpbs.gov.au/internet/independentreviewpbs/publishing.nsf/Content/applicants-seeking-a-review-1lp, consulted on January 1, 2014.

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