

Transparency in pricing arrangements for medicines listed on the Australian Pharmaceutical Benefits Scheme

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Abstract

Australia's system for assessing the cost-effectiveness of drugs for listing under the Pharmaceutical Benefits Scheme (PBS) is recognised internationally. A variety of mechanisms, such as evidence-based rules for determining eligibility for initial or continuing subsidy, price-volume agreements, rebates, and caps on government expenditure are used to contain PBS expenditures. In this paper we assess the extent of use of special pricing arrangements in Australia and how and where they are communicated to health professionals and the community. We searched publicly available documents published by the Pharmaceutical Benefits Advisory Committee (PBAC) and the Pharmaceutical Benefits Pricing Authority (PBPA). We found 73 medicines where special pricing arrangements had been applied and where prices appearing on the Schedule of Pharmaceutical Benefits might differ from those considered to be "cost-effective" by the PBAC. Reporting of these special pricing agreements was inconsistent and generally non-transparent. In some, the lack of transparency may have reflected the desire of manufacturers to disguise the true negotiated price, lest it weaken their negotiation position in other jurisdictions.

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TIMELY ACCESS TO THE MEDICINES that Australians need at a cost individuals and the community can afford is one of the key objectives of Australia's National Medicines Policy; other objectives are appropriate standards of quality, safety and efficacy of medicines, quality use of medicines and maintenance of a responsible and viable medicines industry.¹ While the Therapeutic Goods Administration (TGA) approves a new medicine for registration and marketing, it is the listing of the drug on the Pharmaceutical Benefits Scheme (PBS) that ensures widespread access to the medicine, with taxpayer subsidies and a series of graded copayments that are designed to ensure affordable prices for the individual.

The process of listing on the PBS involves the Pharmaceutical Benefits Advisory Committee (PBAC), which assesses the comparative effectiveness, cost-effectiveness and need for a new medicine in relation to existing therapies. Since 1993 the PBAC has based its judgements on formal cost-effectiveness analysis. The PBAC makes recommendations about the conditions of listing to the Federal Minister for Health and Ageing, and this includes advice regarding a price at which the drug can be considered to offer acceptable "value-for-money".² The success of the methods have led to Australia's system being regarded as a "gold standard" for such programs worldwide,³ and the methods have been adapted for use in other jurisdictions.⁴

There is a less well recognised process that follows a PBAC recommendation for listing to the Minister — negotiation of a final price between the product's sponsor and the Pharmaceutical Benefits Pricing Authority (PBPA). The Baume Report of 1991⁵ resulted in changes to procedures and greater transparency in the operation and decision-making of the TGA. A series of

I Factors considered by the Pricing Authority

- PBAC advice on clinical and cost-effectiveness
- Prices of alternative brands
- Comparative prices of drugs in the same therapeutic group
- Cost data information
- Prescription volumes, economies of scale, expiry dating, storage requirements, product stability, special arrangements
- Level of activity being undertaken by the company in Australia, including new investment, production, research and development
- Overseas prices
- Other factors the applicant may wish the Pricing Authority to cover
- Other directions as advised by the Minister

Source: Pharmaceutical Benefits Pricing Authority. Policies, procedures and methods used in the pricing of pharmaceutical products.¹⁰

reviews of the operations of the PBAC,^{6,7} and provisions contained in the text of the Australia–USA Free Trade Agreement,⁸ have led to greater transparency in its decision-making. This is most obvious in the posting on the Department of Health and Ageing website of details of positive Committee recommendations (since 1999) and decisions to reject applications for listing (since 2004). Public Summary Documents of PBAC decisions have been available on this website since 2005. By contrast, there are few publicly available details on decision-making by the PBPA for individual medicines.

The PBPA publishes Therapeutic Relativity Sheets.⁹ These are written with input from PBAC and provide details of specific therapeutic relativities and pricing comparisons between drugs within a therapeutic group. They form the basis of PBPA pricing decisions. However, the PBPA considers more than therapeutic relativities, using nine criteria, including overseas prices, in their final pricing decisions (Box 1).¹⁰

The PBPA policies, procedures and methods¹⁰ describe two risk-sharing arrangements with industry used by the PBPA — price-volume

agreements with price reductions for sales exceeding a pre-agreed volume, and rebate arrangements with repayment of costs beyond an agreed annual subsidisation cap or threshold. These risk-sharing arrangements have been suggested as one mechanism to contain growth in PBS expenditure.^{2,11,12}

Special pricing arrangements are also used for Section 100 drugs (specialised drugs restricted to supply through hospitals or other specialist facilities).¹³ These include special bonus arrangements where the sponsor lists the drug at its nominated price and provides free goods to the hospital, resulting in an effectively lower cost per unit which is equivalent to the agreed cost-effective price.¹⁰ An alternative mechanism is direct invoice by the manufacturer to Medicare Australia, with an agreed percentage discount to the nominal list price applied at the time of payment.

The numbers of increasingly expensive new biological agents and targeted cancer therapies have brought added pressure to budgets and to decision-making bodies including the PBAC. The prices of these medicines are usually beyond the reach of individual patients and there is pressure for public subsidy. For example, there were sustained media campaigns for subsidisation of trastuzumab (Herceptin)¹⁴ for the treatment of breast cancer, pemetrexed (Alimta) for mesothelioma,¹⁵ and for the inclusion of cervical cancer vaccines (HPV vaccines, Gardasil¹⁶ and Cervarix) and rotavirus vaccines for children¹⁷ in the National Immunisation Program. For several of these there were multiple submissions to the PBAC, suggesting that establishing the case for cost-effectiveness of the medicine was not straightforward.^{16,18,19} In the case of Gardasil, the (then) Minister for Health, Tony Abbott, announced publicly that agreement had been reached on a reduced price for HPV vaccines that included contributions for any booster programs required in the future and towards the costs of setting up a national register to link vaccination data to later cervical screening records.²⁰

In this environment, we sought to examine the extent to which these risk-sharing mechanisms and other special pricing arrangements have been used in recent PBS listing decisions and how and

where these are communicated to health professionals and the community.

Methods

We used two approaches for identifying medicines that might have special pricing arrangements: searching PBAC-related documents and PBPA-related documents separately.

PBAC-related documents: We used publicly available Department of Health and Ageing websites to search for positive outcomes of PBAC meetings (March 2004–July 2008: 14 scheduled meetings; 3 extraordinary meetings),²¹ Public Summary Documents of PBAC decisions (July 2005–July 2008),²² and the Pharmaceutical Benefits Schedule (website and pdf version effective from 1 January 2009)^{23,24} for any mention of special pricing arrangements, price-volume and risk-share agreements, rebate or bonus arrangements, or other references to prices that might be different to those shown in the Schedule of Pharmaceutical Benefits under “Price ex manufacturer” in the case of Section 100 drug listings,²³ or “Dispensed price for maximum quantity” for other listings on the PBS.

PBPA-related documents: We searched PBPA meeting outcomes (December 2005, April 2006, August 2006, December 2006) using the Department of Health and Ageing website²⁵ and hand-searched the Therapeutic Relativity Sheets (August 2007, December 2007, May 2008, July 2008, November 2008)⁹ using the same search strategy outlined above.

Change in use of special pricing arrangements over time: We hypothesised that with the recent proliferation of expensive biological agents and cancer treatments there would be an increasing number of medicines listed with these special pricing arrangements. To examine this, we limited our analysis to major submissions to the PBAC (these require a full economic evaluation) that received a positive recommendation for listing. We calculated the proportion of these major submissions that were listed with a special pricing arrangement for each of the years 2004–2008 separately.

Results

PBAC-related documents

There were 607 positive recommendations by the PBAC from March 2004–July 2008, of which 184 were major submissions (ie, included a full economic evaluation) and 423 were minor submissions. The 184 major submissions were for 148 individual medicines (separate chemical entities). In some cases, there was more than one submission for different indications for use of the medicine.

There were no details of special pricing arrangements for any medicines in the PBAC meeting outcomes. There were 21 mentions of special pricing arrangements in the Public Summary Documents — 15 related to major submissions (13 mentions of risk-share, one price-volume agreement and one reference to a rebate to the PBS from the time of listing); four mentions related to minor submissions (all four were risk-share arrangements). For the latter, while the decision was based on a minor submission, these would have been preceded by a major submission with a full economic evaluation with the minor submission providing additional information requested by the PBAC to enable a positive listing.

Since 2006, the PBAC has assumed responsibility for assessing applications for the listing of vaccines on the PBS and the National Immunisation Program (NIP). The PBAC has approved the listing of two HPV vaccines on the NIP, both of which are subject to risk-share arrangements that were identified in the Public Summary Documents for the products.

There were 11 medicines in the Pharmaceutical Benefits online Schedule that referred to the existence of special pricing arrangements. In each case, these were in the “Notes” field with contents hidden from view until selected by the user. Only one of these medicines was also identified in the Public Summary Documents as having a special pricing arrangement.

Based on the PBAC-related documents examined, there are at least 31 individual medicines (including two vaccines) with special pricing arrangements in place.

2 Examples of pricing details in Therapeutic Relativity Sheets from August 2007 to December 2007*

Drug	Details of pricing arrangements in August 2007
Abacavir	PBS subsidy was affected on the basis that for every three packs of 60 tablets supplied, the PBS would pay for two
Crinone progesterone gel	Listing was achieved through special supply arrangements whereby a 49.5% discount applies to supplies provided under the PBS
Deferasirox	Special supply arrangements are in place whereby a 20% discount applies to supplies of this product under the PBS

* All text changed to "Special Pricing Arrangements Apply" in December version.

PBPA-related documents

There were no details of special pricing arrangements for any medicines in the PBPA meeting outcomes available on the website. There were 55 mentions of medicines with "special pricing arrangements apply" in the Therapeutic Relativity Sheets effective from November 2008. An additional 10 medicines were listed on the basis of cost-minimisation with a medicine that was subject to a special pricing arrangement. It was unclear whether this meant that the new medicine was also subject to a special pricing arrangement. For one further medicine, somatropin, the Therapeutic Relativity Sheet stated that the "price charged by the suppliers per mg of somatropin is identical regardless of the delivery method and/or price quoted in the Schedule of Pharmaceutical Benefits". However, this was one of eleven medicines that were noted in PBS Online as having special pricing arrangements in place.

Eleven of the medicines identified in this PBPA search related to PBS listings before 2004, which had not been recently updated. In summary, there were 55 medicines identified from PBPA-related documents that encompassed the same time period as the analysis of the PBAC outcomes (including the 10 listed on the basis of cost-

minimisation with a medicine with a special pricing arrangement).

Reconciling the results from the two searches, our best estimate is that there are 73 separate medicines listed on the PBS for which special pricing arrangements are in place, 11 listed before 2004 and 62 listed between 2004 and 2008.

Only one medicine, bosentan, was identified as having a special pricing arrangement in all of the relevant documents: PBS Online, the Public Summary Documents and the Therapeutic Relativity Sheets.

Changes in use of special pricing arrangements over time: The proportions of the major submissions for the 148 medicines in our sample with special pricing arrangements by year of positive listing were — 2004: 11/35 (31.4 %); 2005: 5/30 (16.7%); 2006: 13/31 (41.9%); 2007: 10/29 (34.5%); 2008: (incomplete year) 8/23 (34.8%). Overall, almost one-third (47/148, 31.8%) of major submissions to the PBAC in the period 2004–2008 received positive listings with special pricing arrangements in place.

Discussion

Information on "cost-effective" prices being paid by the Australian Government for new medicines is far from transparent. While information on the existence of special pricing arrangements is in the public domain, it is not easily located, and not obvious to the reader of the most logical source of pricing information, the Schedule of Pharmaceutical Benefits. While "special pricing arrangements apply" is noted in the schedule, it is inconsistent, with only 11 of 73 medicines identified in this way.

Even where a special pricing arrangement is identified, there is no detail available on the nature of the arrangements in place. In fact, over time, there has been a reduction in the information available to the public. The Therapeutic Relativity Sheets of August 2007 provided details on the pricing arrangements for seven drugs (see Box 2 for illustrative examples). By the December 2007 version of the Relativity Sheets, these details were replaced by the generic statement "special

pricing arrangements apply". While a special pricing arrangement remains in place for these medicines, it is unclear whether it is different from that described in earlier versions of the Relativity Sheets.

Because of the limited and inconsistent reporting of these special pricing arrangements we cannot be sure we have identified all of the agreements between government and pharmaceutical manufacturers — 73 medicines remains our best estimate of medicines subject to special pricing arrangements. We cannot comment on any variations in prices that might exist between those appearing in the Schedule of Pharmaceutical Benefits and the actual prices determined as cost-effective by the PBAC, and which presumably are the basis of some of the non-transparent pricing arrangements. These differences could be modest or substantial.

Our main analyses relied on specific mention of the medicine and any special pricing arrangements that had been put in place. For a number of other medicines, listing was on the basis of cost-minimisation against medicines that themselves had special pricing arrangements. It was mostly unclear in the public documents whether the newer listed product was subject to a similar arrangement. Simply examining listed prices alone will not answer this question.

It could be argued that the public good in Australia is best served by achieving the lowest possible prices. If so, then the PBPA could be said to be working effectively on behalf of the taxpayer. However, transparent pricing is important in ensuring appropriate and cost-effective use of medications. The successful operation of the pharmacoeconomic requirements of the PBS listing processes depends on a clear definition of the true costs of new pharmaceutical products, by comparison with the drug most likely to be replaced in practice.²⁶ The Australian system requires a sponsor to submit a detailed cost-effectiveness analysis of their product and a suitable comparator. It is not clear that the companies submitting these pharmacoeconomic analyses will be aware of the true acquisition cost of the comparator medicines. If the listed price of the comparator is higher than

the actual price being paid, the calculations of the cost-effectiveness of the new product seeking PBS listing will be flawed.

While prescribers are generally more concerned about out-of-pocket costs to patients than the prices of medicines,²⁷ they cannot be expected to make cost-effective choices if the prices shown to them do not accurately reflect what has been assessed as cost-effective. Consumers are protected by copayments and safety nets that limit their financial exposure to medicine prices, therefore the lack of transparency in pricing may be of little concern to them. Yet transparency matters, is valued and indeed, assumed. In its position statement on medicines, the Australian Medical Association "supports the independence and transparency of PBS listing and pricing functions through the Pharmaceutical Benefits Advisory Committee (PBAC)."²⁸

There is recognition internationally of the importance of greater transparency in the pricing of pharmaceuticals,^{29,30} although the claimed benefits of transparency in increasing efficiency (by promoting price competition), increasing equity (by reducing prices and improving access for the poor), and promoting evidence-based price negotiations are disputed by some.³¹ The primary objective of the Medicines Transparency Alliance (MeTA) is increased transparency with disclosure and use of key pharmaceutical sector information on quality, availability, affordability, access and use of medicines.³²

In Canada, Dhalla and Laupacis³³ have argued that physicians and patients should demand, and participants in the system should provide, transparency in all of the areas of drug approval and reimbursement, including the price determination process. The South African Government has recognised this principle by legislating for a single exit price and transparent margins and fees in the distribution chain in that country.³⁴ Writing in 2004, the Chair of the PBAC, Lloyd Sansom, argued for "the fundamental right of Australian consumers and prescribers to information relevant to decisions about the subsidy of medicines in this country."³⁵ Transparency establishes the legitimacy of decision-making, inspires confi-

dence and trust in the processes, and leads to better decisions. A lack of transparency gives the impression that something is hidden.³³

Australian prices are used in international benchmarking to determine reimbursement prices elsewhere.³⁶ Dhalla and Laupacis note that prices for “breakthrough” drugs in Canada are linked to the median prices for the same drug in seven different countries and caution that undisclosed deals between pharmaceutical companies and public payers may result in artificially inflated prices in Canada.³³ A similar warning was echoed in a recent OECD report.³⁷ The 2001 Productivity Commission report noted that international price benchmarking may provide an incentive for sponsors to post high list prices (especially in those countries that are used as international benchmarks), but to offer discounts and other less transparent forms of price reductions to buyers.³⁸

The World Health Organization/Health Action International (WHO/HAI) database has been described as crucial for fostering increased transparency on essential drug and product pricing.³⁹ The methods used by WHO/HAI are based on comparisons with an international reference price to derive median price ratios.³⁹ Most surveys are conducted using Management Sciences for Health (MSH) reference prices.⁴⁰ New Zealand Pharmaceutical Management Agency (PHARMAC) and Australian PBS prices are the two nominated alternative sets of reference prices that might be used. In addition to WHO/HAI surveys, there have been ad-hoc studies comparing medicine prices in Australia and elsewhere.^{38,41} Increasingly, the PBS-listed price may not represent the cost-effective price for these comparisons, this lack of price transparency obscuring international price comparisons.

The history of risk-share arrangements in Australia is relatively short. A 2006 Australian National Audit Office (ANAO) report⁴² states the first formal risk-share arrangement between the Department of Health and a sponsor company was signed in 2003, with a further 14 signed in the period 2003–2005. The use of special pricing arrangements has grown apace since then, with

the proportions of new medicines being listed with special pricing arrangements now around 30%. The ANAO has recommended periodic review of the utility of these measures to assess their impact on PBS cost.⁴²

Collier describes the Pharmaceutical Price Regulation Scheme operating in the UK since 1956 as non-statutory (a gentleman’s agreement), secretive, perverse, anti-competitive and anti-democratic.⁴³ While the premises under which the Australian and UK systems operate differ considerably, some of the descriptors may be applicable to these commercial in confidence pricing arrangements in Australia, which are obscured from competitors and prescribers and the general public whose taxes support the system.

All of this is occurring at a time when the PBAC has responded to calls for greater transparency in decision-making and makes the reasons for its decisions public. The “secrecy” in pricing for new medicines is in stark contrast to the approaches being used by the Australian Government in relation to prices for generic medicines. One of the intents of the 2006 PBS reforms⁴⁴ was price disclosure, so government payments for medicines were more closely aligned to pharmacy purchase prices for generic medicines. This was in part a response to assertions of “secret deals”, “kick backs” and discounts to pharmacists by manufacturers of generic medicines.⁴⁵

It is likely that use of special pricing arrangements will continue. In principle, these are not a bad thing if they lead to lower priced medicines and lower costs for consumers. But the details should be known to everyone and made available in publicly accessible sites. While the fine details of the commercial arrangements will probably remain secret, that a medicine is subject to a pricing arrangement should not, and the true acquisition cost should be visible. At a minimum, the Schedule of Pharmaceutical Benefits should identify the medicines affected and it should be clear that the publicly listed price does not reflect what has been determined as a cost-effective price, that is, the true subsidised price for the medicine.

Competing interests

The University of Newcastle has a contract with the Australian Government Department of Health and Ageing to review submissions to the Pharmaceutical Benefits Advisory Committee. David Henry was Chair of the Economics Sub-Committee of the PBAC and member of the PBAC 1995–2000. The views expressed in this paper are solely those of the authors and not of the University of Newcastle or the Australian Government Department of Health and Ageing.

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