

**Cost Effectiveness Analysis and the
Consistency of Decision Making:
Evidence from Pharmaceutical
Reimbursement in Australia 1991-96**

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ABSTRACT

The Commonwealth Government of Australia subsidises the price that consumers have to pay for drugs that are listed on the Pharmaceutical Benefits Schedule (PBS). Drugs can only be listed on that schedule once a pharmaceutical company has made a submission to the Pharmaceutical Benefits Advisory Committee (PBAC). Economic evaluation has been a mandatory part of that submission since 1993. This paper investigates whether decisions made by the PBAC are consistent with the evidence about the cost-effectiveness of that drug supplied by the pharmaceutical company.

The paper also discusses whether the advice given by the PBAC to list a drug on the PBS reveals a threshold incremental cost-effectiveness ratio beyond which the PBAC is not prepared to recommend reimbursement.

Method: All 355 submissions made to the PBAC between 1991 and June 1996 were reviewed. Submissions were ranked in a league table by incremental cost per life year gained (26 submissions) or the cost per QALY gained (9 submissions) and compared with advice given by the PBAC about that drug.

Results: The main observation from the league table is that between 1991 and 1996 the PBAC cost-effectiveness threshold range lay between \$37,000 and \$69,000 per extra life year gained. Some drugs with an incremental cost per extra life year gained less than this were not recommended for listing suggesting that the cost effectiveness ratio was not the only factor determining the reimbursement decision. Other factors considered include the quality of life years gained, the quality of the evidence, the nature of the condition and the availability of substitute therapies, and the financial implications to government.

Key Words

Cost-effectiveness; reimbursement; pharmaceuticals; decision making; league tables

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Cost Effectiveness Analysis and the Consistency of Decision Making

Evidence from Pharmaceutical Reimbursement in Australia 1991-1996

Introduction

Economic evaluation in the form of cost effectiveness analysis, has become a popular means to inform decisions about priority setting in health care. There are, however legitimate doubts as to the influence that these studies have had on policy[1]. Economic evaluation has had the most obvious direct influence on public decision making in the areas of technology assessment and pharmaceuticals. For example, since 1993 Australia has required pharmaceutical companies to include an economic evaluation of their product with each submission to the Pharmaceutical Benefits Advisory Committee (PBAC) prior to reimbursement on the Pharmaceutical Benefits Schedule (PBS). Other governments in Canada (CCOHTA, 1994) New Zealand (PHARMAC, 1993) and the United Kingdom (Department of Health, 1994) have also developed guidelines for economic evaluation.

Cost Effectiveness Analysis Efficiency and Decision Making

While the principle of allocating scarce resources on the basis of cost benefit analysis is well established, there are a number of practical and ethical problems in estimating and using economic appraisal for priority setting in health. The most obvious is the difficulty in estimating the monetary value of non-market goods in the health sector and particularly health outcomes. For this reason very few studies in health have used cost-benefit analysis [2] although there has been a revival of interest in placing money values on health outcomes [3], [4], [5], [6]. There has also been a growing interest in cost utility analysis which uses preference weights to construct an index of outcome combining length of life with its health related quality [7]. The dominant methodology in health however has been cost-effectiveness analysis, because of the difficulties in measuring appropriate prices or preferences for health states. Outcome measures typically used for cost-effectiveness have been life years saved or surrogate clinical endpoints such as ulcers cured or blood pressure reduction.

Cost-effectiveness analysis is limited, however, to interventions with homogeneous outcomes, and so its results cannot easily be compared across diagnostic groups, or across sectors of the economy. Optimal decision rules for achieving economic efficiency using cost-effectiveness analysis are well established [8], [9]. Cost-effectiveness ratios for outcomes measured in the same units (or cost-utility ratios) can be listed from lowest to highest in the form of a 'league table'. Provided these programs display constant returns to scale, the league table can, in theory be used to allocate a budget across programs efficiently. In the presence of a fixed budget, programs can be implemented in sequence from the top down until the budget is exhausted, maximising economic efficiency. The last program chosen within the budget determines a cut off value or shadow price of the health gain.

If the common outcome is incremental life-years gained or incremental QALY's gained, the last program chosen demonstrates how much the decision maker is willing to pay for a year of life, or a QALY respectively. The simple case of a decision-maker faced with a fixed budget and a complete set of divisible alternative interventions with known costs and outcomes is rare. The more usual approach is to use a critical or cut off value of the cost effectiveness ratio derived from other than the true shadow price of the marginal intervention. Weinstein [10] identifies a number of approaches used to derive this cut off value of which perhaps the three most common are comparisons with other programs, rules of thumb, and inference from past decisions. This paper explores the possibility of deriving such a cut off value from past decisions made by the PBAC.

League Tables and Priority Setting

Decision-makers will naturally look for some indication of the opportunity cost of an intervention in the relative cost effectiveness of other programs. Williams, in 1985, published the first QALY league table, a rank order of cost-utility ratios [11], and more have followed [12], [13]. Table 1, shows an example of a league table developed for Australian health care interventions.

The validity of any attempt to combine the results of cost-effectiveness studies must depend in part on the consistency of the methodology used. Mason has recommended a minimum data set to be included for each entry into a cost-effectiveness league table (Table 2), if useful comparisons are to be made between therapeutic interventions [14]. In practice this minimum dataset is not usually available. Studies combined in league tables to date have used different methods to measure effectiveness and have been undertaken in a variety of different health care systems and medical practices. Interpretation of these tables is extremely difficult and caution is necessary if league tables are to be used as decision making tool [15], [16]. In short, the validity of a league table and any implications drawn from it is constrained by the quality and consistency of the underlying studies, and most tables to date are of limited value to decision makers.

Drummond argues that "theoretically a cost per QALY league table can provide comprehensive and valid information to inform resource allocation decisions." At the same time he admits that "such a table would require listing of all existing and potential treatments, for all patient groups, at all feasible levels of program scale or intensity, calculated using standardised comparable methods [16]. The theoretical and practical problems with using a league table approach to

prioritisation have also been discussed in the context of the Oregon experiment [17]. Even where similar interventions are evaluated in the same country the methods of costing may differ and the quality of the evidence on efficacy may not be of the same standard. Decision-makers cannot possibly imagine and compute all possible combinations of interventions or programs in order to make decisions in an incremental fashion. Timely data could never be made available and problems arise if there are economies of scale or some programs are fixed in size.

Ultimately, in the absence of a fixed budget, the league table is not decisive in determining whether an intervention should be implemented and the decision on which programs to implement requires an independent judgement about the marginal willingness to pay for health gains. Programs can then be implemented from the top of the list stopping where the marginal project has a cost per health gain equal to this pre-defined shadow price.

For a cost-effectiveness league table to be used as a tool in priority setting, in the absence of a fixed budget, decision-makers need to determine a threshold price that reflects their marginal willingness to pay for health gains.

In this context, we report a new national league table of cost effectiveness of drug interventions, together with details of its source, the Australian process for listing new drugs onto its national drug subsidy scheme. In 1993, the Commonwealth Government of Australia made economic evaluation mandatory for pharmaceutical companies submitting a drug to PBAC, to be listed on the PBS. The PBS began in the 1950's and aims to provide reliable access to affordable medicines for the Australian community. The Australian consumer only contributes a fixed amount towards the full cost of drugs listed on the PBS, the government funds the rest. It is, therefore, the PBS drugs that are prescribed most often. There are around 1600 products listed on the PBS.

The Australian government was the first in the world to draw up guidelines for economic evaluation of pharmaceuticals [18]. An amendment was made to section 101 of the National Health Act (1953) [19], [20] which now requires the PBAC to consider comparative costs and effectiveness before deciding to list a new drug on the PBS. Submissions are evaluated by the Pharmaceutical Evaluation Section (PES) who assess the validity of the data presented, checking for errors of fact, statistics and inference and provide a summary of the information and remaining uncertainties for the PBAC.

The PBAC uses the information from each submission to help decide whether to recommend the inclusion of the proposed drug on the PBS. The final price for the drug is then negotiated between the manufacturer and the Pharmaceutical Benefits Pricing Authority (PBPA). The evaluation of cost-effectiveness of a new drug is therefore made on the basis of a nominated price. Sensitivity analysis on price may allow the PBAC to calculate value for money of the drug at a range of prices and provide advice to the PBPA on that basis. However, the PBPA is obliged to take into account factors other than the PBAC's comments on therapeutic relativity and cost-effectiveness.

One objective of developing guidelines in Australia was to encourage companies to produce consistent economic analyses using recommended techniques. Ranking drugs for which a

submitted cost-effectiveness analysis has conformed with a set of guidelines and which has then been rigorously assessed by an independent team of evaluators should, in theory, increase the validity of that ranking. While there is a certain amount of flexibility within the guidelines, which means that the results are still not entirely homogeneous, they do represent a more uniform league table than one created by a cull of the literature.

Aims

A League Table of Decisions

The principle aim of this study was to generate a cost-effectiveness or cost-utility league table of drugs considered by the PBAC for reimbursement. The paper discusses whether the league table can be combined with past listing decisions on reimbursement to infer a threshold value of cost per additional life year (or cost per QALY gained).

Consistency with Economic Efficiency

A related aim of the paper is to consider the consistency of the decision making process itself. The paper tests the hypothesis that the cost effectiveness ratios do not distinguish those drugs that were recommended for listing from those which were not. The authors recognise however that some decisions taken by the PBAC may be inconsistent with economic efficiency as a single or over-riding objective. Apparent inconsistencies in the league table may indicate the presence of other decision criteria such as equity, a version of the rule of rescue [21], or the overall financial implications of reimbursement.

Methods

All 355 consecutive submissions to the PBAC for the period January 1991 to June 1996 were reviewed for the outcome measures used in the economic evaluations. Outcome measures are normally summarised by the PES as part of the clinical evaluation they provide to the PBAC. Where outcome measures could not be identified easily from the PES summaries the submissions themselves were consulted. The main problem encountered at this stage was with the reporting of the cost-effectiveness ratios. Wide ranges were reported for costs and outcomes, usually as the result of a sensitivity analysis, and there were discrepancies between company estimates of cost-effectiveness ratios and those recalculated by the PES. Where more than one estimate of the incremental ratio was presented, the ratio reported by the PES was recorded for this study. Submissions presenting incremental cost-effectiveness ratios for extra life years gained or extra QALY's gained were grouped to form two league tables. For reasons of confidentiality (subsection 135A(1) of the Commonwealth Government of Australia National Health Act 1953, neither the drug name or the indication for which it may be prescribed can be presented in these league tables.

All incremental costs were inflated to 1995/96 prices using the GDP deflator [22]. Given that the most distant year in either league table was 1992, this adjustment made little impact. Although

listed drugs do not tend to change in price over time other components of the treatment costs do. Since one aim of the paper is to examine the range of cut off cost-effectiveness ratios, they are best described in constant prices.

The null hypothesis, that there is no difference between the cost per life year gained for drugs which were recommended for listing and those which were not, was tested using the Mann-Whitney test. Submissions were ranked by cost per extra life year gained. “Recommended at lower price” and “reject” decisions were treated as not recommended and the defer decision was discarded. The cost per life year gained was compared between the groups recommended and not recommended.

Data

A submission made to the PBAC must contain information on the pharmacology, proposed course of treatment, proposed indications for the drug, any adjunct therapies which may be required and a nomination of the main comparator. The submission needs to produce a list of all existing randomised trials comparing the proposed drug with its main comparator and a description of the search strategy used to obtain these trials. Data on comparative clinical effectiveness and safety should be presented primarily from this source and synthesised where appropriate using meta-analysis. Economic evaluation based on these trials needs to be performed, analysed and interpreted, in addition to presenting any modeled economic evaluation. Finally, details of the full financial implications to the PBS of listing the proposed drug are required.

The cost effectiveness ratios have all been calculated to conform with the Guidelines produced by the PBAC [18]. Unlike other league tables the data is from one jurisdiction, over a defined period of time, with a considerable degree of consistency. All the included studies should have:

- a) similar types of comparators;
- b) calculated incremental cost effectiveness ratios;
- c) a societal perspective which includes public and private health costs;
- d) used the same unit cost data with a 5% annual discount rate and in constant prices;
- e) unit costs of treatments based on a Manual of Resource Items provided to the companies by the PBAC;
- f) have the same evidentiary requirements for outcome effect size;
- g) calculated incremental costs including all medical and non medical costs associated with the drug treatment and its comparator;
- h) not included productivity losses, non-health related resource use, and unrelated health costs.

The data on outcomes in PBAC submissions is largely based on clinical endpoints with a hierarchy of acceptable evidence as described in the Guidelines [18]. Data on life threatening diseases is available in the form of incremental life years saved and is the largest group used in the league table reported below. The number of cost-utility analysis submitted to the PBAC is

growing, but in the period of this study most of these have weak theoretical validity and rely largely on hypothetical utility values based on third party opinion. For this reason the PBAC may have been skeptical about the quality of the evidence in these studies.

The guidelines are not prescriptive, however the practical result of the detailed advice provided is akin to providing the kind of reference case suggested by the Washington Panel [23]. Where there was a deviation from the guidelines the PES recalculated the cost-effectiveness ratio to conform with the standard methods.

Results

Table 3 contains a summary of the submission types and analyses types encountered during the study (for definitions see appendix 1). Some submissions contained ratios for two or more outcomes; six submissions provided both an incremental cost-utility ratio and an incremental cost per extra life year gained ratio. The league tables created for incremental life years gained and incremental QALY's gained are shown in Tables 4 and 5 respectively. Very generally, the indications for which some estimate of incremental life years or QALY's gained were available included malignant disease, drugs for HIV and associated conditions and some miscellaneous drug treatments. These two disease groups are not unexpected, because in both these conditions, subjects may only require relatively short follow up periods to obtain survival data and there is a greater body of experience in quality of life assessments among such patients.

The results in Table 4 show a range of incremental costs per extra life year gained from \$5,050 to \$235,200 Australian dollars (at 1995 prices). Of the 26 submissions shown, around half were recommended for listing at the nominated price. No drug was recommended at the nominated price with an incremental cost-effectiveness ratio more than \$68,913. With one exception, no drug was rejected with an incremental cost-effectiveness ratio less than \$36,450. The hypothesis test allowed a rejection of the null hypothesis of no association between the cost-effectiveness ratio and the decision to recommend listing ($p=0.0008$).

Table 5 indicates that only one drug was rejected on the basis of its cost-utility ratio. Given the small number of studies, and a relatively narrow range of cost per QALY gained, no conclusions can reasonably be drawn from Table 5 about the implicit value of health gains.

Some attempts were made to construct rankings by cost-effectiveness ratio of drug and disease classes where surrogate outcomes had been measured. Although there are surrogate outcomes that are common to two or more submissions in a therapeutic group, there are neither enough submissions per group nor enough common outcomes to form a sensible ranking. This approach may have some potential in the future but we were unable to use the results in this study.

Discussion

Ranking the Results of Submissions to the PBAC in a League Table

A major motivation for the Australian Government in producing guidelines for the economic evaluation of pharmaceuticals was to increase the consistency of subsequent submissions both with each other and with economic theory. As discussed above, ranking the resulting incremental cost-effectiveness ratios to create a league table should, in theory, have considerable face validity. The biggest problem with this approach is that while companies may have used the consistent methodology and data on resource use recommended in the guidelines, the current guidelines do not specify a single common outcome measure. The result is that while it was possible to identify two common outcomes (life years and QALY's) and to generate league tables from a proportion of PBAC data, outcome measures are not homogeneous across all submissions. Only 8% of the major submissions to the PBAC between 1991 and June 1996 (and only 23% of incremental economic evaluations submitted) could be included in the league tables.

Incremental Cost-Effectiveness Ratios and Decision Making

There is a difference between the incremental cost-effectiveness ratios of drugs that were recommended at price and drugs that were not recommended. This supports the observation that the decisions to recommend drugs at a proposed price are associated with lower costs per life year gained than decisions to reject or recommend listing at a lower price. This is consistent with the use of economic efficiency as a criterion for decision making.

To date the PBAC appears to have a threshold range between \$37,000 and \$69,000 per extra year of life gained. An important caveat on these results is that estimates of extra life-years gained contain no adjustment for the quality of those years of life. It is possible that drugs in table 4 were rejected, not because of high cost per year of life saved, but because the committee considered that the quality of the life years saved was low. Thus the committee's threshold for a cost per life year saved, when adjusted for the quality of that life, could be above \$69,000. We were unable to derive any implicit value from the submissions that used QALY's as outcomes because an insufficient number of submissions with cost-utility analyses have been lodged to date.

Policy Relevance

Notwithstanding the caveat above, the data in this retrospective review do suggest an implicit threshold range for cost-effectiveness ratios. Since the values are an implication of past decisions rather than a considered introspection on the part of the committee, it is not clear whether they provide policy makers with a cut-off value useful in other health care decisions. Only to the extent that consistency in decision making is desirable, the context is comparable, and the values revealed considered reasonable, will the implied values be likely to influence future policy.

Decisions Consistent with Economic Efficiency

The results in table 4 suggest that the PBAC has been generally consistent with efficiency as a single objective in its use of economic evaluation. However, this objective alone cannot adequately explain the reasons for the Committee's decisions, particularly within the range where cost-effectiveness ratios have fallen between \$37,000 and \$69,000 per additional life year gained. There are a number of apparent inconsistencies for the drugs whose ratios fall between these two figures. Therefore, although broadly consistent with an efficiency objective, these tables also demonstrate that the PBAC does not operate against a fixed willingness to pay threshold as an absolute decision rule. While this may suggest that the PBAC is being inconsistent in meeting an efficiency objective, there are a number of other explanations. A complete analysis of the interplay between these alternative explanations for these apparent inconsistencies is outside the scope of this paper, however at least three can be suggested. First, presenting a single ratio for each submission does not indicate the uncertainty that could be reflected in the sensitivity analyses concurrently presented to the PBAC. Uncertainty may also arise where in some cases technical flaws in the economic evaluation have had a large impact on the ratio forcing the committee to reject the presented ratio as unacceptable. In the face of such uncertainty, decision-makers tend to respond in a risk-averse manner. Second, if the extra life-years gained were likely to be associated with poor quality of life (and in the absence of data to suggest otherwise), implicit quality-weighting by the committee could have increased the corresponding cost-utility ratios to an unacceptably high level. Last, the PBAC Guidelines refer to a number of other factors that the Committee considers being also relevant. These may result in trade-offs between competing objectives, which include:

- a) the scientific rigour and relevance of evidence for comparative safety, efficacy and cost-effectiveness of the drug;
- b) the lack, or inadequacy of alternative treatments currently available;
- c) the perceived need in the community;
- d) if the drug is likely to only be used in hospital setting only and
- e) the seriousness of the intended indication.

The decisions which result may be quite consistent with a wider range of objectives that go beyond simply maximising health gain at minimum cost. The PBAC has begun to review such decisions and recognises that it may be possible to make these other factors more explicit in its decision making.

Conclusions

Are League Tables Useful?

Priority setting has become extremely important to health care policy makers in the light of rapidly developing health care technologies and public pressure to contain health care costs. Health care rationing has previously been an implicit role of health care practitioners at the clinical level. The emphasis now, however, is to use a logical and consistent process to make those decisions more transparent. In creating this process, decision-makers must be wary of placing too much weight on ratios based on a limited information set and containing implicit value judgements. The danger of producing league tables is not that decision-makers might start to believe them, but that they may begin to act on them without regard to considerations beyond economic efficiency. Smith puts the problem “once complex administrative decisions have been reduced to a simple and usually quantified, comparison of costs and benefits it would seem irrational...not to act in accordance with the numbers” [24]. However in re-stating the decision making approach to cost-benefit analysis, Williams argues that cost-utility analysis is not intended to be a solution to a political problem but only a means by which to explore analytically decisions which might be made [25]. In the context of this paper, ranking the cost-effectiveness results with decisions made by the PBAC may shed some light not only on whether they have been acting in a way consistent with economic efficiency, but also on the factors which they regard as important beyond cost-effectiveness.

It is clear from the results of this study that decisions to recommend a drug for listing by the PBAC in the last few years have, by and large, been consistent with the notion of economic efficiency. That is to say subject to a few important caveats it has been possible to identify a range beyond which the PBAC has not been willing to pay for life years gained. The results also suggest that economic efficiency is not the only factor that the committee considers when assessing drugs proposed for listing on the PBS. In addition to the quality of the submitted data the committee may consider the nature of the condition and whether there are alternative treatments available. There may even be an interaction of factors. For example, the PBAC might be more likely to recommend a treatment for a relatively rare but severe condition where there is no alternative, even if this drug appears to be comparatively inefficient. They may also on occasion have considered issues of equity (however this is defined), access and affordability from the patient perspective, and financial implications for government. Given all of these it is perhaps even more surprising that the decisions illustrated in this study are so consistent with a single objective of economic efficiency.

Where Do We Go From Here?

Public decisions in health care are rarely taken with any consideration of economic efficiency. Even where costs are considered public decisions are, on the whole, made in an incremental fashion with varying levels of evidence and different decision making processes. The public decision making process with regard to the reimbursement of pharmaceuticals in Australia, however, does appear to be internally consistent with a set of value judgements which include

economic efficiency. The paper has emphasised that economic efficiency is only one factor in the decision making process and so far the analysis has been limited to drugs with a measurable impact on survival. It may be possible to devise a categorisation of common outcomes that would allow comparisons to be made within drug classes. Alternatively it may be possible to investigate cost-effectiveness cut off values from other broader sources of the social willingness to pay for health gains, for example through population survey techniques [26]. Whatever route is taken, the results of this study provide some encouragement both about the consistency of public decision making and the use of economic appraisal to promote efficiency in health care.

Table 1 Comparative Australian Cost-Utility/Cost-Effectiveness Results

Program	Adjusted cost per life year or per QALY at 1995-96 prices
Health promotion programs	
Sydney quit smoking campaign	\$19 per life year
Non-drug blood pressure reduction clinic	\$5,969 per life year
Care/cure programs	
Neonatal intensive care, babies 1000-1500g	\$1,433-3,582 per life year
Kidney transplant	\$5,455 per life year
Neonatal intensive care, babies <801g	\$4,298-5,492 per life year
Breast cancer screening	\$7,879-13,132 per life year
Cervical cancer screening	\$36,749 per life year
Hospital dialysis	\$57,053 per QALY
AIDS treatment with zidovudine	\$155,201 per life year

Source: Cervical cancer screening in Australia: Options for change [13]
Prices adjusted using the GDP deflator (ABS Economic Indicators) [22]

Table 2 A Minimum Dataset For Each Entry in a Cost-Effectiveness League Table.

1	A precise definition of the intervention (who got what, where and when)
2	A precise definition of the baseline, or alternative treatment
3	A summary of the date and country of origin of the medical resource data, and funding agencies
4	A summary of the quality of medical evidence
5	A summary of the estimation of quality of life effects
6	A summary of the way the medical evidence has been used (ie modelling assumptions)
7	A summary of cost measurement, duration, inclusions, assumptions, currency, conversions and reflation
8	A description of the discount rates used
9	A summary of the cost-utility ratio
10	A sensitivity analysis to investigate the importance of items 4-8 above

Source: Mason 1994 [14]

Table 3 **A Summary of Major Submissions and Analysis Types**

	Submissions
	n (%)
Type of Major Submission	
New	223 (63)
Re-submission	73 (21)
Change	33 (9)
Refer	20 (6)
PBPA matter	6 (2)
Form of Economic Analysis	
Cost-effectiveness	125 (35)
Cost-utility	9 (3)
Cost-minimisation	98 (28)
Pseudo Cost-effectiveness	86 (24)
Other*	37 (10)

* Other = 36 submissions without an economic evaluation lodged in 1991 and 1992 before economic evaluations became mandatory, and 1 cost-benefit analysis

Table 4 Incremental Cost per Additional Life Year Gained League Table

Number	Incremental cost per additional life year gained at 1995-96 prices	PBAC decision
1	5,050	Recommend at price
2	7,665	Recommend at price
3	8,000	Recommend at price
4	15,915	Recommend at price
5	17,174	Recommend at price
6	17,376	Recommend at price
7	18,130	Recommend at lower price
8	20,371	Recommend at price
9	24,531	Recommend at price
10	35,000	Recommend at price
11	36,450	Recommend at price
12	39,083	Reject
13	39,864	Reject
14	39,864	Defer
15	39,864	Recommend at price
16	51,420	Reject
17	53,000	Recommend at price
18	58,311	Reject
19	65,523	Recommend at price
20	68,913	Recommend at price
21	78,157	Recommend at lower price
22	81,343	Reject
23	90,000	Reject
24	209,674	Recommend at lower price
25	212,041	Reject
26	235,200	Reject

Table 5 **Incremental Cost per Additional QALY Gained League Table**

Number	Incremental cost per additional QALY gained at 1995-96 prices	PBAC decision
1	4,293	Recommend at price
2	4,800	Recommend at price
3	7,845	Recommend at price
4	9,639	Recommend at price
5	12,010	Recommend at price
6	16,419	Recommend at lower price
7	19,428	Recommend at price
8	22,282	Recommend at price
9	122,050	Reject

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Submission Types [18]

New – Applications made for a new drug or a new formulation of a currently listed drug for which a price premium is requested

Change – Applications made for a significant change to the listing of a currently restricted drug (new indication or de-restriction) or to enable a review of the comparative cost-effectiveness of a currently listed drug in order to change a PBAC recommendation to the PBPA on its therapeutic relativity or price premium

Resubmission – Applications for reconsideration by the PBAC. May be based on entirely new data, present modifications to the previously requested indication or changes to the comparator

Refer – Any submission arising from a matter referred to the sponsor by the PBAC

PBPA matter – Any submission arising from the activities of the PBPA

Economic Evaluation Types [18]

Cost-minimisation – The proposed drug is demonstrated to be at least no worse therapeutically than other drugs at the same or a lower price. Assuming the PBAC accepts the alternative therapies as providing acceptable outcomes for their cost, a new treatment which offers these outcomes at a lower cost is preferable.

Cost-effectiveness – The proposed drug is demonstrated to offer more of a given outcome. This goes beyond cost-minimisation, for example, a drug may have a higher requested price but achieve the desired clinical outcome in a higher proportion of patients than the alternative therapy. The outcome indicators reported from the randomised trials may need to be adapted in a modelled cost-effectiveness analysis, and where this is done the choice of outcome should be justified. The summary measure of cost-effectiveness is the incremental cost per additional unit outcome achieved.

Cost-utility – Presents the outcomes in terms of an extension of life and a utility value of that extension. Cost-utility analysis should report the changes in activities of daily living or other methods used to project the weighted outcomes.

Pseudo cost-effectiveness – Presents qualitative arguments for cost-effectiveness of a drug in terms of potential advantages which seem likely, but are not yet demonstrated and for which no quantitative estimates are yet available. These submissions should now be classified as *partial evaluations*