Drew Carter, Arlene Vogan, Hossein Haji Ali Afzali

**Governments need better guidance to maximise value for money: the case of Australia's Pharmaceutical Benefits Advisory Committee**

Applied Health Economics and Health Policy, 2016; 14(4):401-407

‘Current opinion’ in *Applied Health Economics and Health Policy*

# Governments need better guidance to maximise value for money: the case of Australia’s Pharmaceutical Benefits Advisory Committee

Running head: Governments need better guidance to maximise value for money

Drew Carter [1]
Arlene Vogan [2]
Hossein Haji Ali Afzali [1]

(1) School of Public Health, University of Adelaide, Adelaide, Australia
(2) Adelaide Health Technology Assessment, School of Public Health, University of Adelaide, Adelaide, Australia

Corresponding author:

Drew Carter
Email: drew.carter@adelaide.edu.au
Telephone: +61 8 8313 0620

## Abstract

In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to the Minister for Health on which pharmaceuticals should be subsidised. Given the implications of PBAC recommendations for government finances and population health, PBAC is required to provide advice primarily on the basis of value for money.

The aim of this article is twofold: to describe some major limitations of the current PBAC decision-making process in relation to its implicit aim of maximising value for money; and to suggest what might be done toward overcoming these limitations. This should also offer lessons for the many decision-making bodies around the world which are similar to PBAC.

The current PBAC decision-making process is limited in two important respects. First, it features the use of an implicit incremental cost-effectiveness ratio (ICER) threshold that may not reflect the opportunity cost of funding a new technology, with unknown and possibly negative consequences for population health. Second, the process does not feature a means of systematically assessing how a technology may be of greater or lesser value in light of factors that are not captured by standard measures of cost effectiveness, but which are nonetheless important, particularly to the Australian community. Overcoming these limitations would mean that PBAC could be more confident of maximising value for money when making funding decisions.

## Key Points for Decision Makers:

- The current decision-making process of Australia’s Pharmaceutical Benefits Advisory Committee (PBAC) is limited in relation to its implicit aim of maximising value for money.

- The decision-making process features the use of an implicit incremental cost-effectiveness ratio threshold that may not reflect the opportunity cost of funding a new technology; moreover, it does not feature a means of systematically assessing how the value of a technology may differ in light of important factors not captured by standard measures of cost effectiveness.
- Some attempts have been made outside of Australia to overcome such limitations, and if similar attempts were undertaken in Australia, PBAC could be more confident of maximising value for money when making funding decisions.

**Compliance with Ethical Standards**

Funding: Drew Carter and Hossein Haji Ali Afzali are supported by the 'Health Care in the Round' Capacity Building Grant in Population Health (National Health and Medical Research Council Grant ID 565501).

Conflict of Interest: Drew Carter has acted as a consultant to Adelaide Health Technology Assessment (AHTA) on assessments undertaken for the Pharmaceutical Benefits Advisory Committee (PBAC). Arlene Vogan is an employee of AHTA, an independent academic group contracted by the Department of Health to conduct or evaluate health technology assessments for the listing of pharmaceuticals and other health technologies on behalf of the PBAC and the Medical Services Advisory Committee (MSAC). Hossein Haji Ali Afzali is a member of the Evaluation Sub-Committee (ESC) of the MSAC. The opinions expressed in the article are those of the authors.

## 1 Introduction

In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) makes recommendations to the Minister for Health on which pharmaceuticals should be subsidised under the Pharmaceutical Benefits Scheme (PBS). In the year to 30 June 2014, $9 billion was spent on pharmaceuticals through the PBS [1]. Given the implications of the PBS for government finances and population health, PBAC is required to provide advice primarily on the basis of value for money. In assessing this, PBAC considers a range of factors, including safety, clinical effectiveness, cost effectiveness (including the magnitude of uncertainty pertaining to incremental cost and effect estimates) and budget impact [2].

One key aspect or dimension of the value provided by a technology lies in its direct health benefit or improvement. In most cases, the preferred unit of health improvement is the quality-adjusted life-year (QALY). But there are other aspects or dimensions of value. For example, a technology may provide value by functioning to reduce health inequalities, especially those associated with socio-economic status or geographic area (urban as distinct from rural, for instance). In Australia, asthma, lung disease and arthritis are more prevalent in rural areas [3], therefore funding drugs to treat these diseases could help to reduce health inequalities. Society values such things, which are not readily captured through use of the QALY as a measure of value.

Submissions for government subsidy serve to provide PBAC with *evidence* about the proposed pharmaceutical. Ideally, this evidence speaks to the *criteria* that PBAC members use to determine whether government subsidy is warranted. But for PBAC members to meaningfully apply criteria, they require *standards*. The evidence can then be used to determine whether a technology meets the standards. In other words, the evidence submitted may indicate how ‘good’ a proposed pharmaceutical is, but a decision maker needs some notion of when a technology is ‘good enough’ [4]. There is simply no other way to make a decision.

The aim of this article is twofold: to describe some major limitations of the current PBAC decision-making process in relation to its implicit aim of maximising value for money; and to suggest what might be done toward overcoming these limitations. This should also offer lessons for the many decision-making bodies around the world which are similar to PBAC.

## 2 The current cost-effectiveness threshold does not reflect opportunity cost

Most new pharmaceuticals are both more effective and more costly than their comparators. Formal economic evaluation is used to assess whether the additional benefits are worth the additional costs. This assessment is reported in terms of a new pharmaceutical’s incremental cost-effectiveness ratio (ICER). The ICER represents the additional cost of producing an additional unit of ‘effect’ (one QALY) through use of a new technology instead of a comparator. The appraisal of whether a new pharmaceutical is good *enough* to subsidise requires comparison of its ICER with some *standard* (some threshold) representing the maximum acceptable numerical value for the ICER of a new technology.

Many countries, including Australia and the UK, have a constrained pharmaceuticals budget system in which the costs of new technologies tend to be met through a combination of displacement and budget increases. In such a system, the opportunity cost of choosing to fund

a new technology falls on other health (or non-health) areas, resulting in benefits (e.g. QALYs) foregone – for example, through the displacement of health promotion or preventive programmes. Therefore, the decision maker's ICER threshold ideally reflects the *opportunity cost* of choosing to fund a new technology [5-7]. Choosing to fund a new technology only when its ICER compares favourably to (falls below) *the ICER threshold that reflects opportunity cost* ensures that the health gains associated with the new technology (at a given price) are greater than the health benefits foregone by displacing existing technologies. This ensures a net gain in QALYs across the health system. If technologies are funded with ICERs that compare unfavourably to (exceed) the threshold, then the QALYs foregone will exceed those gained from funding the new technology, resulting in a net loss of QALYs, i.e. a decrease in population health [7].

Several approaches have been used to determine the numerical value of the ICER threshold. The World Health Organization advocates the use of a threshold that is tied to a nation's GDP [8], while others have focussed on the societal willingness-to-pay for a QALY, as estimated using revealed-preference methods [9]. However, these approaches will not necessarily identify an ICER threshold that reflects the opportunity cost of funding a new technology. Therefore, these approaches will not necessarily help to increase population health every time a funding decision is made.

PBAC has never acknowledged the use of an ICER threshold [10]. However, some threshold (some standard) is *required* to make a yes-or-no funding decision, even if the threshold is implicit and vague [4, 11]. Indeed, past PBAC funding decisions suggest the use of an implicit threshold. The submission to PBAC of brentuximab vedotin (BV) for the treatment of systemic anaplastic large-cell lymphoma in March 2014 reported an ICER in the range of $75,000 to $105,000 per QALY gained. PBAC responded that "at the price proposed in the submission, BV was not acceptably cost-effective", but that "BV would be cost-effective at a reduced price that produced an ICER … of between $45,000 and $75,000/QALY" [12]. Likewise, when considering whether the government should fund pomalidomide for the treatment of multiple myeloma in July 2014, PBAC recommended that "a price reduction would be required to achieve an ICER in the range of $45,000 – $75,000/QALY" [13]. These examples, among others, clearly suggest that PBAC uses an ICER threshold (in the form of a numerical range) to assess pharmaceuticals for their value for money. Moreover, these examples suggest that, when submissions contain ICERs that exceed the threshold, PBAC invites price reductions geared toward meeting the threshold.

Other examples further suggest that PBAC uses an ICER threshold. When considering whether the government should fund erlotinib for the treatment of unselected non-small cell lung cancer in March 2014, PBAC deemed that "the most likely ICER at the current erlotinib price (at greater than $90,000/QALY) was unacceptably high" [14]. Likewise, when considering whether the government should fund abiraterone acetate for the treatment of prostate cancer in July 2014, PBAC deemed that the ICER "was within the range $105,000 – $200,000/QALY" and that this was "unacceptably high" [15]. The use of terms such as "unacceptably high" entails a comparison between a technology's ICER and some threshold denoting a minimum standard.

Retrospective analysis of PBAC decisions suggests that pharmaceuticals are likely to be recommended for funding when ICERs fall below $42,000 per life-year gained, and that pharmaceuticals are unlikely to be recommended for funding when ICERs exceed $76,000 per life-year gained [16]. This numerical range appears to have been inferred from previous

PBAC decisions, with no conceptual or empirical foundation concerning the opportunity cost of funding a new technology within the current health system. While PBAC's approach may achieve consistency in decision making over time, it does not necessarily maximise value for money. Seemingly arbitrary thresholds, as used in the UK and Canada, have been observed to lead to increases in health care expenditure without evidence of increases in population health [5, 17].

## 3 Aspects of value not readily captured through use of the QALY are not assessed systematically

The use of an ICER threshold that reflects the opportunity cost of funding a new technology will serve to maximise the direct health benefits that follow from funding decisions in terms of QALYs gained. However, there are other aspects or dimensions of value provided by a health technology. The QALY does not capture all aspects of value relevant to funding decisions. Therefore, to maximise the number of QALYs gained is not necessarily to maximise value for money.. For instance, society may attribute more value to an expenditure that secures fewer QALYs but directs these to the people worst off. This is the case with Australian society [18].

The ICER is only one of several inputs to the decision-making process. PBAC recognises that decision makers should consider more than just QALYs [19]. PBAC submission guidelines invite comment on factors beyond clinical and cost effectiveness if these may be relevant to the funding decision, explicitly mentioning equity, the severity of the medical condition, and whether effective alternatives to the proposed pharmaceutical are available [2]. If a proposed pharmaceutical meets such criteria, then PBAC may recommend funding despite a high ICER.

This is evident in recent examples of PBAC decision making. When considering whether the government should fund everolimus for the treatment of renal cell carcinoma in March 2014, PBAC noted that the pharmaceutical's ICER was "lower than between a range of $75,000 to $105,000/QALY, but higher than between a range of $45,000 to $75,000/QALY" [20]. PBAC found that "given the clinical need for treatments in this population of patients … at the price proposed in re-submission, everolimus was acceptably cost-effective" [20]. During the same meeting, PBAC also recommended funding ivacaftor for the treatment of cystic fibrosis. This submission presented an ICER that exceeded $100,000/QALY, but PBAC recommended funding in the context of high clinical need and strong patient support for subsidised access, albeit with additional risk-sharing measures imposed [21, 22]. Similarly, PBAC has recommended funding in a number of cases that have featured high ICERs (albeit within the range of $45,000–$75,000/QALY), citing high clinical need, a lack of alternative treatments, small patient numbers, and a modest overall cost (i.e. budget impact) [23-27]. Indeed, analyses suggest that budget impact has been an important determinant of PBAC decision making [28, 29].

The Life Saving Drugs Programme (LSDP) is an alternative funding mechanism for pharmaceuticals with ICERs much higher than those normally accepted. The programme is government-run and, in 2014, PBAC took over decision making responsibility. Pharmaceuticals must meet eligibility criteria, some of which concern the absence of alternative treatments, the cost burden to the patient or family in the absence of government subsidy, and the characteristics of the disease (it must be rare and cause a significant

reduction in life expectancy) [30]. To demonstrate that these and other eligibility criteria are met, applicants must provide relevant evidence, which can then be systematically assessed as part of the decision-making process. In this way, the LSDP process itself functions to identify and collect evidence on factors besides clinical and cost effectiveness. This situation contrasts with the submission process for listing on the PBS, where the onus is on the *applicant* to identify any relevant factors besides clinical and cost effectiveness [2]. Because of this, it is unclear whether other factors are considered by PBAC systematically (outside of the LSDP) and how much their consideration actually affects decisions.

While other factors can enter into PBAC decision making, there are limitations regarding how consistently and transparently they do so. For typical (non-LSDP) submissions, PBAC does not appear to have a framework specifying what other factors ought to enter into decision making, when they ought to do so, and what importance they ought to be accorded relative to one another and relative to clinical and cost effectiveness. In other words, decision makers receive little guidance, and little restriction, when it comes to assessing how a technology may be of greater or lesser value in ways not captured by standard measures of cost effectiveness. This means that the standard measures of cost effectiveness shape decisions either too much or not enough, as other factors are either under-emphasised or over-emphasised by decision makers on the day.

Since there is little transparency regarding what factors actually enter into PBAC decision making and how they do so, there is also little known about how well the values of the Australian community are reflected. While community views are sought as part of the PBAC decision making process, current consultation processes may not capture views reflective of the broader Australian community, since vested interests are most likely to provide input [19]. This means that decision makers can draw on values not shared by the broader community when assessing a technology's value for money.

## 4 How can these limitations be overcome?

These limitations of the PBAC decision-making process point to the challenges of appropriately utilising economic evidence and of integrating it with factors of importance beyond its scope. These challenges are not isolated to Australia, and some attempts to address them have been made overseas.

In recent years, the UK's National Institute for Health and Care Excellence (NICE), which issues guidance on what technologies should be funded though the National Health Service (NHS), has explicitly acknowledged the use of an ICER threshold with the numerical value of £20,000-30,000/QALY [31]. When a technology's ICER falls below £20,000/QALY, the decision to fund is based simply on this estimate of cost effectiveness. However, within the range of £20,000-30,000/QALY, technologies may be funded subject to their meeting further, explicit criteria, some of which concern the degree of confidence in the ICER estimate, whether changes in health-related quality of life have been adequately captured, the innovative nature of the technology, and whether aspects of the technology relate to broader social objectives [31, 32]. Life-extending treatments at the end of life are considered "very important" [33], and so additional value is attributed to these treatments, such that funding can be commended in the face of an ICER as high as £50,000/QALY [34, 35]. These treatments must be for patients with a short life expectancy, treatment must offer an extension to life of at least three months, and the indicated population must be small [31].

Claxton et al. recognised not only that the ICER threshold should reflect the opportunity cost of introducing a new technology into a constrained-budget system [36], but also that a sound empirical basis is needed to estimate the numerical value of this threshold [7]. To this end, Claxton et al. developed robust methods to estimate the relationship between marginal changes in health expenditure and health outcomes, adjusting for quality of life. This approach estimated that the numerical value of the UK's ICER threshold should be £12,936/QALY, which is significantly lower than the £20,000-30,000/QALY currently used [7]. Further research is required to improve on study limitations, including assumptions on quality-of-life effects [37]. But the study fostered discussion on the need for clarity about the ICER threshold. If the current, implicit threshold used by PBAC is too high, then its downstream impact on population health could be substantial. For example, if PBAC used a threshold of $60,000/QALY, then a decision to fund a new pharmaceutical with this ICER and an additional cost of $18m per year would result in a gain of 300 QALYs across the health system. However, if the PBAC threshold should actually be $30,000/QALY, given the opportunity cost of funding a new technology in the current health system, then the additional cost associated with choosing to fund this pharmaceutical would lead to a loss of 600 QALYs across the health system, and a net loss of 300 QALYs for every additional $18m allocated to the new pharmaceutical. The decrease in population health follows from having to forego the greater benefits of the technologies being displaced by the new pharmaceutical.

To determine what community values should be considered during NICE decision making, a standing Citizens Council is formed to gain a public perspective. The Council consists of 30 members of the public who largely reflect the demographic characteristics of the UK. The recommendations of the Council form the broad social-value principles that NICE takes into consideration when making decisions [38]. The overarching intention of applying such principles is not purely to produce decisions that more closely align with social values. It is also to temper the pursuit of efficiency, considered simply in terms of the maximisation of QALYs gained, with the pursuit of equity, considered in terms of the just distribution of those QALYs across social and patient groups, especially favouring the worst off [39].

Other countries use alternative approaches to integrate social values into decision making and achieve greater equity. In New Zealand, the Pharmaceutical Management Agency (PHARMAC) currently considers nine criteria when making decisions. These include health needs, particularly of Māori and Pacific peoples, the availability and suitability of existing treatments, and the safety, effectiveness and cost effectiveness of the proposed technology [40]. Where applicable, the importance of each criterion is deliberatively weighted as deemed appropriate by PHARMAC [40]. These criteria are under review, and proposals have been made to extend them to 15 in number. Proposed criteria encompass the need, health benefits, suitability, costs and savings attaching to new treatments relative to the individual, wider society and the health system. These criteria have been informed by public consultation, involving more than 300 people at 12 community forums, though it is not yet clear how so many criteria will be handled in practice [41].

The UK and New Zealand approaches suggest that different ICER thresholds may be acceptable if the value of a QALY can be adjusted in line with defensible social judgements. If these judgements can be *quantified*, then numerical weights can be applied to a cost-effectiveness analysis, either through adjusting the QALY gains or the ICER threshold. In the Netherlands, a quantitative approach has been advocated, whereby necessity has been conceptualised in terms of "proportional shortfall" [42]. The approach prioritises patients

who are expected to lose the greatest proportion of their remaining (quality-adjusted) life expectancy due to disease, if left untreated. It would allow the ICER threshold to vary depending on the necessity of the technology, as determined by the proportional shortfall of the relevant population.

Multi-criteria decision analysis (MCDA) also provides a formal approach to the systematic consideration of multiple factors relevant to decision making. Relevant criteria are identified then assigned a weight based on their relative importance. The performance of a technology is then scored against each criterion, with the relative weights applied to derive an overall score. A framework has been developed to apply MCDA to Health Technology Assessment [43]. If input is provided by the community regarding the relevant criteria and their relative importance, then MCDA can reflect community values. However, decision makers may lack confidence in the methods used to obtain numerical values in MCDA. Decision makers may regard deliberation as preferable, because it may not be possible or practical to meaningfully quantify the importance of all relevant factors. A broad-brush approach may be preferred, and the UK example of using different, explicit ICER thresholds according to the other factors in play seems to represent such an approach.

## 5 Conclusions

The current PBAC decision-making process is limited in two important respects. First, it features the use of an implicit ICER threshold that may not reflect the opportunity cost of funding a new technology, with unknown and possibly negative consequences for population health. Second, the process does not feature a means of systematically assessing how a technology may be of greater or lesser value in light of factors that are not captured by standard measures of cost effectiveness, but which are nonetheless important, particularly to the Australian community. Overcoming these limitations would mean that PBAC could be more confident of maximising value for money when making funding decisions. While the focus of this article has been on PBAC decision making, the same limitations apply to the decision-making processes of most national funding bodies around the world.

## Acknowledgments

We thank Suzanne Dyer for research assistance and Annette Braunack-Mayer, Jonathan Karnon and Tracy Merlin for formative discussion.

## Author contributions

Drew Carter and Hossein Haji Ali Afzali made substantial contributions to the conception and plotting of the manuscript, to the analysis and interpretation of data, and to critical revision of the manuscript so as to contribute to its interpretation. Arlene Vogan made substantial contributions to the analysis and interpretation of data, and drafted and critically revised the manuscript so as to contribute to its interpretation.

**References**


1. Australian Government Department of Health. Expenditure and Prescriptions twelve months to 30 June 2014. Commonwealth of Australia, Canberra. 2015. http://www.pbs.gov.au/info/statistics/expenditure-and-prescriptions-30-06-2014. Accessed June 2015.

2. Australian Government Department of Health. Guidelines for preparing submissions to the Pharmaceutical Benefits Advisory Committee. Commonwealth of Australia, Canberra. 2013. http://www.pbac.pbs.gov.au/home.html. Accessed Feb 2015.

3. Australian Institute of Health and Welfare. Chronic conditions. 2015. http://www.aihw.gov.au/rural-health-chronic-conditions/.

4. Giacomini M. How good is good enough? Standards in policy decisions to cover new health technologies. Healthc Policy. 2007;3(2):91-101.

5. Gafni A, Birch S. Incremental cost-effectiveness ratios (ICERs): the silence of the lambda. Social science & medicine. 2006;62(9):2091-100. doi:10.1016/j.socscimed.2005.10.023.

6. Culyer A, McCabe C, Briggs A, Claxton K, Buxton M, Akehurst R et al. Searching for a threshold, not setting one: the role of the National Institute for Health and Clinical Excellence. Journal of health services research & policy. 2007;12(1):56-8. doi:10.1258/135581907779497567.

7. Claxton K, Martin S, Soares M, Rice N, Spackman E, Hinde S et al. Methods for the estimation of the NICE cost effectiveness threshold. CHE Research Paper 81. York: Centre For Health Economics, University of York 2013.

8. World Health Organization. Macroeconomics and Health: Investing in Health for Economic Development. Report of the Commission on Macroeconomics and Health. Geneva: World Health Organization 2001.

9. Simoens S. How to assess the value of medicines? Frontiers in pharmacology. 2010;1:115. doi:10.3389/fphar.2010.00115.

10. Bulfone L, Younie S, Carter R. Health technology assessment: reflections from the Antipodes. Value Health. 2009;12 Suppl 2:S28-38. doi:10.1111/j.1524-4733.2009.00556.x.

11. Drummond M, Sorenson C. Nasty or nice? A perspective on the use of health technology assessment in the United Kingdom. Value Health. 2009;12 Suppl 2:S8-13.

12. Pharmaceutical Benefits Advisory Committee. Public Summary Document. Brentuximab Vedotin, 50 mg injection, 1 x 50 mg vial Adcetris® - March 2014. Commonwealth of Australia, Canberra. 2014. http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2014-03/brentuximab-vedotin-psd-03-2014. Accessed Feb 2015.

13. Pharmaceutical Benefits Advisory Committee. Public Summary Document. 5.13 POMALIDOMIDE, capsules, 3 mg and 4 mg, Pomalyst®, Celgene Pty Ltd. - July 2014. Commonwealth of Australia, Canberra. 2014. http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2014-07/pomalidomide-psd-07-2014.pdf. Accessed Feb 2015.

14. Pharmaceutical Benefits Advisory Committee. Public Summary Document. Erlotinib, 25 mg tablet, 30, 100 mg tablet, 30 and 150 mg tablet, 30, Tarceva®, Roche Products Pty Limited - March 2014. Commonwealth of Australia, Canberra. 2014. http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2014-03/erlotinib. Accessed Feb 2015.

15. Pharmaceutical Benefits Advisory Committee. Public Summary Document. 6.1 ABIRATERONE ACETATE, tablet, 250 mg, Zytiga®, Janssen-Cilag Pty Ltd - July 2014. Commonwealth of Australia, Canberra. 2014. http://www.pbs.gov.au/industry/listing/elements/pbac-meetings/psd/2014-07/abiraterone-psd-07-2014.pdf. Accessed Feb 2015.

16. George B, Harris A, Mitchell A. Cost-effectiveness analysis and the consistency of decision making: evidence from pharmaceutical reimbursement in australia (1991 to 1996). PharmacoEconomics. 2001;19(11):1103-9.

17. Birch S, Gafni A. The biggest bang for the buck or bigger bucks for the bang: the fallacy of the cost-effectiveness threshold. Journal of health services research & policy. 2006;11(1):46-51. doi:10.1258/135581906775094235.

18. Richardson J, Sinha K, Iezzi A, Maxwell A. Maximising health versus sharing: measuring preferences for the allocation of the health budget. Soc Sci Med. 2012;75(8):1351-61. doi:10.1016/j.socscimed.2012.05.036.

19. Whitty JA, Littlejohns P. Social values and health priority setting in Australia: An analysis applied to the context of health technology assessment. Health policy. 2014. doi:10.1016/j.healthpol.2014.09.003.

20. Pharmaceutical Benefits Advisory Committee. Public Summary Document. EVEROLIMUS, tablets, 5 mg and 10 mg, Afinitor®, Novartis Pharmaceuticals Australia Pty Ltd - March 2014. Commonwealth of Australia, Canberra. 2014. http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2014-03/everolimus-rcc. Accessed Mar 2015.

21. Pharmaceutical Benefits Advisory Committee. Public Summary Document. Ivacaftor, 150 mg tablet, 56, Kalydeco® - March 2014. Commonwealth of Australia, Canberra. 2014. http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2014-03/ivacaftor-psd-03-2014. Accessed Feb 2015.

22. Pharmaceutical Benefits Advisory Committee. Public Summary Document. Ivacaftor, tablet, 150 mg, Kalydeco® - July 2013. Commonwealth of Australia, Canberra. 2013. http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2013-07/ivacaftor. Accessed Feb 2015.

23. Pharmaceutical Benefits Advisory Committee. Public Summary Document. Infliximab, powder for IV infusion, 100 mg, Remicade® - March 2010 Commonwealth of Australia, Canberra. 2010. http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2010-03/pbac-psd-Infliximab-mar10. Accessed Mar 2015.

24. Pharmaceutical Benefits Advisory Committee. Public Summary Document. ROMIPLOSTIM, powder for injection, 100 micrograms, 250 micrograms and 500

micrograms, Nplate® - July 2010 Commonwealth of Australia, Canberra. 2010. http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2010-07/pbac-psd-Romiplostin-july10. Accessed Mar 2015.

25. Pharmaceutical Benefits Advisory Committee. Public Summary Document. Sunitinib malate, capsule, 12.5 mg, 25 mg and 50 mg (base), Sutent® - July 2012. Commonwealth of Australia, Canberra. 2012. http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2012-07/sunitinib. Accessed Feb 2015.

26. Pharmaceutical Benefits Advisory Committee. Public Summary Document. Pazopanib, film-coated tablets, 200 mg and 400 mg (as hydrochloride), Votrient® - July 2013. Commonwealth of Australia, Canberra. 2013. http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2013-07/pazopanib. Accessed Feb 2015.

27. Pharmaceutical Benefits Advisory Committee. Public Summary Document. Everolimus, tablets, 2.5 mg, 5 mg and 10 mg, Afinitor® - April 2013. Commonwealth of Australia, Canberra. 2013. http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2013-04/everolimus. Accessed Mar 2015.

28. Mauskopf J, Chirila C, Masaquel C, Boye KS, Bowman L, Birt J et al. Relationship between financial impact and coverage of drugs in Australia. Int J Technol Assess Health Care. 2013;29(1):92-100. doi:10.1017/s0266462312000724.

29. Chim L, Kelly PJ, Salkeld G, Stockler MR. Are cancer drugs less likely to be recommended for listing by the Pharmaceutical Benefits Advisory Committee in Australia? Pharmacoeconomics. 2010;28(6):463-75. doi:10.2165/11533000-000000000-00000.

30. Australian Government Department of Health. Life Saving Drugs Program Criteria and Conditions. Commonwealth of Australia, Canberra. 2013. http://www.health.gov.au/internet/main/publishing.nsf/Content/lsdp-criteria. Accessed Feb 2015.

31. National Institute for Health and Care Excellence. Guide to the methods of technology appraisal 2013. National Institute for Health and Care Excellence, London. 2013. https://www.nice.org.uk/article/pmg9/chapter/6-the-appraisal-of-the-evidence-and-structured-decision-making. Accessed Mar 2015.

32. National Institute for Health and Care Excellence. Social Value Judgements: Principles for the development of NICE guidance. National Institute for Health and Care Excellence, London. 2013. https://www.nice.org.uk/proxy/?sourceUrl=http%3a%2f%2fwww.nice.org.uk%2fmedia%2fC18%2f30%2fSVJ2PUBLICATION2008.pdf. Accessed Mar 2015.

33. National Institute for Health and Care Excellence. NICE statistics. National Institute for Health and Care Excellence, London. 2014. http://www.nice.org.uk/News/NICE-statistics. Accessed Feb 2015.

34. National Institute for Health and Care Excellence. NICE consults on new draft recommendations for lung cancer drug. National Institute for Health and Care Excellence,

London. 2013. https://www.nice.org.uk/news/press-and-media/nice-consults-on-new-draft-recommendations-for-lung-cancer-drug. Accessed Feb 2015.

35. The Pharmaceutical Journal. NICE puts brakes on its planned overhaul of drugs evaluation processes. Royal Pharmaceutical Society. 2014. http://www.pharmaceutical-journal.com/news-and-analysis/news/nice-puts-brakes-on-its-planned-overhaul-of-drugs-evaluation-processes/20066537.article. Accessed Mar 2015.

36. Longworth L, Sculpher MJ, Bojke L, Tosh JC. Bridging the gap between methods research and the needs of policy makers: a review of the research priorities of the National Institute for Health and Clinical Excellence. International journal of technology assessment in health care. 2011;27(2):180-7. doi:10.1017/S0266462311000043.

37. Barnsley P, Towse A, Karlberg S, Sussex J. Critique of CHE Research Paper 81: Methods for the estimation of the NICE Cost Effectiveness threshold. Occasional Paper 13/01. London: Office of Health Economics 2013.

38. National Institute for Health and Care Excellence. Citizens Council. National Institute for Health and Care Excellence, London. 2014. http://www.nice.org.uk/get-involved/citizens-council. Accessed Feb 2015.

39. Culyer AJ. The bogus conflict between efficiency and vertical equity. Health Econ. 2006;15(11):1155-8. doi:10.1002/hec.1158 [doi].

40. Pharmaceutical Management Agency. Making funding decisions. Pharmaceutical Management Agency, Wellington. 2014. http://www.pharmac.health.nz/assets/factsheet-04-making-funding-decisions.pdf. Accessed Feb 2015.

41. Pharmaceutical Management Agency. Changing the way we make decisions. Pharmaceutical Management Agency, Wellington. 2015. http://www.pharmac.health.nz/medicines/how-medicines-are-funded/factors-for-consideration/. Accessed Feb 2015.

42. van de Wetering EJ, Stolk EA, van Exel NJ, Brouwer WB. Balancing equity and efficiency in the Dutch basic benefits package using the principle of proportional shortfall. The European journal of health economics : HEPAC : health economics in prevention and care. 2013;14(1):107-15. doi:10.1007/s10198-011-0346-7.

43. Goetghebeur MM, Wagner M, Khoury H, Levitt RJ, Erickson LJ, Rindress D. Bridging health technology assessment (HTA) and efficient health care decision making with multicriteria decision analysis (MCDA): applying the EVIDEM framework to medicines appraisal. Medical decision making : an international journal of the Society for Medical Decision Making. 2012;32(2):376-88. doi:10.1177/0272989X11416870.