

# Experience from an Australian Perspective

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## Disclaimer

- The opinions expressed in this presentation are solely the views of the author
- These do not necessarily reflect the views of the Australian Government, Department of Health, or the Pharmaceutical Benefits Advisory Committee.

# Overview

- Background to HTA and pharmaceutical subsidy processes in Australia
- Use of QALYs
- ICER Thresholds
- Culture?

## Pharmaceutical Benefits Scheme (PBS)

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- Established in 1948 and governed by the *National Health Act 1953*
- Australian Government subsidised national 'formulary' for community use
  - entire population have access
  - modest patient co-payment (currently \$6.20 or \$38.30)
- In 2014-15
  - >1000 different drugs; 3,288 forms/strengths
  - 288 million scripts
  - AU\$9.1 billion cost to government



# Regulatory framework – pharmaceuticals

- 1992: Australia became the first country in the world to require evidence on cost-effectiveness for government subsidy of pharmaceuticals
- PBS not capped
- Drug choices still required

## Pharmaceutical policy in Australia

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- National Medicines Policy (2000)
  1. Universal access at reasonable cost
  2. Appropriate standards for quality, safety, efficacy
  3. Quality use of medicines
    - Judicious
    - Appropriate
    - Safe
    - Effective
  4. Maintain responsible and viable medicines industry



## Australian Government HTA policy framework

Vision (2009):

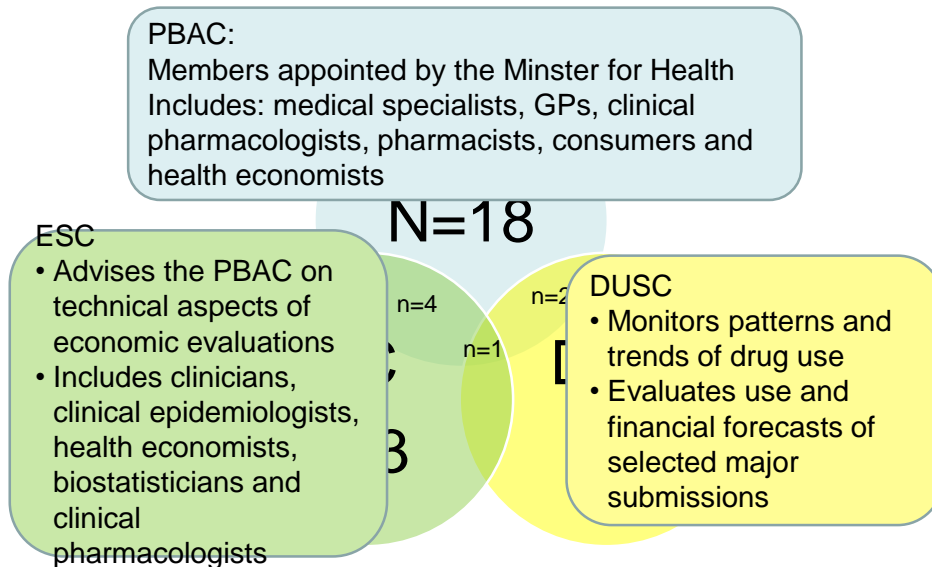
*“Australians have timely, equitable and affordable access to the cost-effective health technologies needed to manage their health.”*



## Pharmaceutical Benefits Advisory Committee (PBAC)

- Independent statutory body
- Recommends drugs and medicinal preparations to the Minister for funding under the PBS
- Recommends vaccines for funding under the National Immunisation Program (since 2006)

# PBAC and sub-committees



## PBAC recommendation criteria include:

- Comparative Health Gain (Effectiveness, safety)
- Comparative Cost Effectiveness
- Financial implications for PBS & Gov health budget
- Severity of condition treated
- Presence of effective alternatives
- Ability to target therapy to those likely to benefit most
- Uncertainty
- Equity
- “Rule of Rescue” - May be favourable to listing as a supplement to other considerations in exceptional circumstances
  - No alternative treatment exists in Australia
  - Condition is severe, progressive and expected to lead to premature death
  - Condition applied to only a very small number of patients

Source: PBAC Submission Guidelines 2008

## Example of a positive recommendation

<p>Imatinib, tablet, 100mg and 400 mg, (as mesylate), Glivec®</p> <p>Novartis Pharmaceuticals Australia Pty Ltd</p> <p>Minor submission</p>	<p>Anti-cancer drug</p>	<p>Resubmission for an Authority Required listing for the adjuvant treatment of an adult patient at high risk of recurrence following complete resection of primary gastrointestinal stromal tumour which has been histologically confirmed by the detection of CD117 on immunohistochemical staining, at a dose not exceeding 400 mg/day for a period of 12 months.</p>	<p>The PBAC recommended listing on the basis of an acceptable cost-effectiveness ratio compared with placebo.</p>
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<http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/2011-03/positive-recommendations>

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## Example: decision not to recommend

<p>Cladribine, tablet, 10 mg, Movectro®</p> <p>Merck Serono Australia Pty Ltd</p> <p>Major submission</p>	<p>Multiple sclerosis</p>	<p>Section 100 listing for the initial and continuing treatment of relapsing – remitting multiple sclerosis (RRMS) initiated by a neurologist, in an ambulatory patient who has experienced at least two documented attacks of neurological dysfunction, believed to be due to multiple sclerosis in the preceding two years who meets certain criteria.</p>	<p>The PBAC rejected the submission because of use of an inappropriate comparator, uncertain clinical benefit and uncertain and unacceptable cost effectiveness in comparison with the appropriate comparator. The appropriate main comparator is interferon beta, the most commonly used first line treatment for multiple sclerosis.</p>
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- Inappropriate comparator
- Uncertain clinical benefit
- Uncertain and unacceptable cost-effectiveness

<http://www.pbs.gov.au/pbs/industry/listing/elements/pbac-meetings/pbac-outcomes>

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## Use of QALYs?

### Percentage of all submissions to the PBAC:

- Early 1990's = 2.5% (George et al, *Pharmacoecon* 2001)
- 2002-04 = 21.3% (Scuffham et al, *Pharmacoecon* 2008)
- March 2016 = 37.8% (Public Summary Documents)
  - 52.9% of Major submissions
  - NB: remainder of submission contain cost-minimisation, cost-effectiveness, or are a “minor” submission without an economic evaluation.

## Availability of country-specific value sets

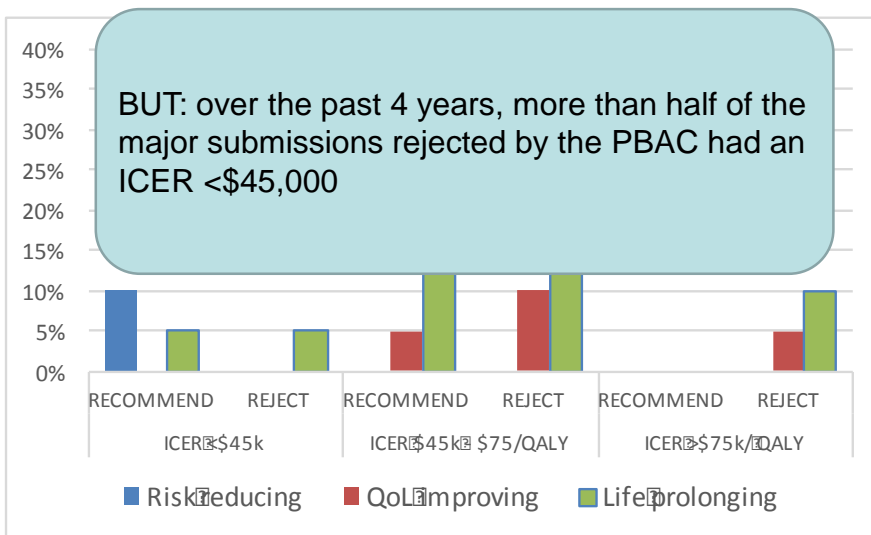
### Value sets derived from Australian populations

- AQoL
  - 1999: Hawthorne et al. *Qual Life Res* (TTO)
- EQ-5D-3L
  - 2011: Viney et al. *Value in Health* (TTO)
  - 2013: Viney et al. *Health Economics* (DCE)
- EQ-5D-5L
  - 2013: Viney et al. *Appl Health Econ Health Policy* (DCE)
- SF-6D (SF-36)
  - 2014: Norman et al. *Med Decis Making* (DCE)

# PBAC Thresholds?

- 1991-96: (George, Pharmacoeconomics, 2001)
  - >\$72,000 – unlikely to recommend
  - <\$42,000 unlikely to reject
- 1994-2004: (Harris et al, Med Decis Making, 2008)
  - \$46,400
    - Life-threatening condition increased prob by 0.38
- March 2016 (public summary documents):
  - Categorised by
    - preventive / risk reducing
    - QoL improving
    - Life prolonging

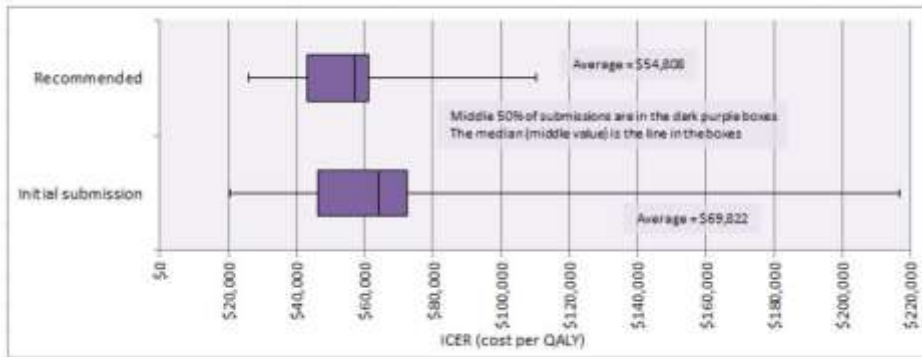
## PBAC recommendations PSDs - March 2016





# Cancer drugs

**Figure 3.2: ICERs for first cancer submissions vs. recommended cancer submissions**



Source: Department of Health, Submission 197, p. 31.

50% of recommended applications are in the range of \$42 000-\$61 000

## Can this approach be explained by culture, values and institutional context?

- YES:
  - Australia is very institutionalized, bureaucratic, and tightly regulated
  - High level of evidence-based decision-making
  - Value-based pricing?
  - Industry are part of the process and culture
- HOWEVER:
  - CUA and use of QALYs are only one criteria in the decision-making process
- Committee will discuss and compare clinical outcomes of other drugs in the same class

Are there features of the approach in your country that cannot easily be explained?

- No:
  - Alternatives, such as the efficiency frontier approach, were unlikely to have been considered in the 1990's when the PBAC was being established
  - Relative value for money is a fundamental premise for spending public funds

Are there any arguments for a change in approach, based on culture, values of institutional context?

- No, but maybe yes?
  - the norm is equivalent cost for equivalent benefit (value-based pricing)
  - Frontier approach within drug class maybe "as good" as CEA
  - ? too much bureaucracy can be inefficient and delay getting drugs to those who need them in a timely manner!
  - BUT PBAC process is well established and relatively efficient given the level of evidence required for decision-making

- Thank You