

# Implementing guidelines for reimbursement in Australia

## How the PBAC & MSAC use comparative cost- effectiveness

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## Access to medicines, devices and procedures in Australia

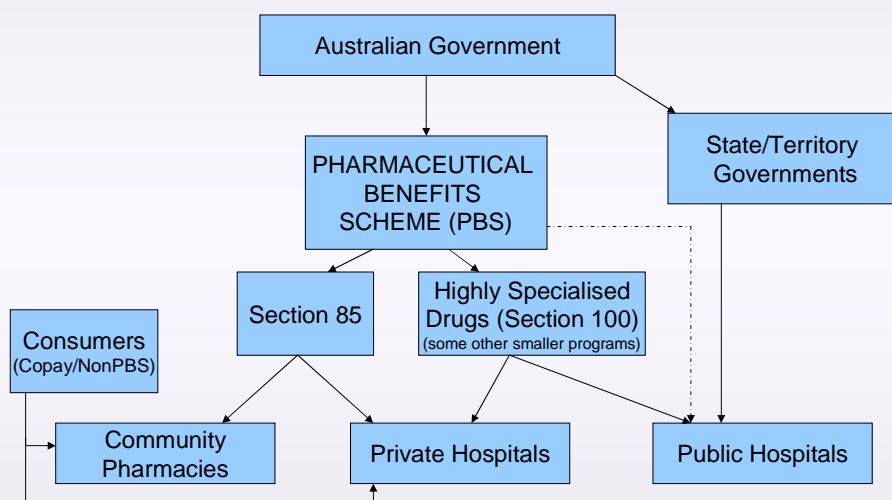
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- Two stage system
  - Access
  - Subsidised access
- 1) Registration (licensing approval) by Therapeutic Goods Administration (TGA)
  - Efficacy, safety, quality
- 2) Subsidised access to **listed drugs** through the Pharmaceutical Benefits Scheme (PBS);  
Subsidised access to **devices and procedures** through the Medical Benefits Scheme (MBS).

## About the Pharmaceutical Benefits Scheme

- National scheme in operation since 1948
- Open-ended funding
- Subsidised access to pharmaceuticals
  - 665 different drugs (June 2006)
  - 168 million scripts (05/06)
  - Au\$6.2 billion cost to government (05/06)
    - 17% of government health budget
    - 7.8% of Australian health expenditure
- PBAC “recommends”
  - comparative effectiveness, comparative safety, comparative costs

## Who pays for medicines?



## Role of the PBAC

- Consider and evaluate submissions (requests for listing)
  - Drugs can only be listed on the PBS following positive recommendation by PBAC
- Legislative requirement for consideration of comparative costs and effectiveness in recommending drugs (since 1987)
- A new drug may be recommended for listing if:
  - Needed for prevention or treatment of significant medical conditions not already covered or inadequately covered, *and is of acceptable cost-effectiveness*
  - More effective and/or less toxic than a listed drug, *and is of acceptable cost-effectiveness*
  - At least as effective and safe as a listed drug, *and is of similar or better cost-effectiveness*
- Make recommendations about pricing matters referred by PBPA
- Since 2005-6 PBAC can also initiate reviews of drugs or classes of drugs
- Since 2006 PBAC processes apply to vaccines, including for the National Immunisation Program

## Economic evaluation and PBAC

- Pharmaceutical Benefits Advisory Committee (PBAC)
  - makes recommendations about allocation of resources to and between medicines
- Economic evaluation (formal requirement since 1993)
  - Informs decisions about “acceptable cost-effectiveness”
  - Answers questions of technical and (to some extent) allocative efficiency
  - Does not address issues of equity
- PBAC **is** concerned with efficiency and equity
  - Committee judgment
  - Other relevant factors

## Economic Sub-Committee of PBAC

- ESC is a technical committee
- Comprises clinicians, epidemiologists, pharmacologists, biostatisticians and economists
- **Undertakes prior technical assessment** of the submission and the commentary
  - Uses advice from independent groups of academic evaluators
- Provide ESC advice to PBAC on clinical and economic aspects
  - Particularly on the nature of the evidence and on key areas of clinical and economic uncertainty
- **ESC does not make recommendations about listing**,
  - Identify all issues that are relevant to the decision
  - Aiming to ensure all relevant information is available by PBAC meeting
- Also provides advice about other issues
  - Particularly guidelines, methodological developments

## Economic Evaluation

- Stepped economic evaluation
  - From the clinical trial results to the model
  - Designed to make explicit the impact of the assumptions made in the pre-modelling studies
- Explicit preference for CUA in most cases
  - where there is a claim of life-years gained to assess the impact of QOL for the survival gain
  - where there is a claim of improvement in QOL
  - where relevant direct randomised trials report results using a MAUI
- CUA not mandated
  - Where there is a high degree of uncertainty about the translation to QALYs may be less informative

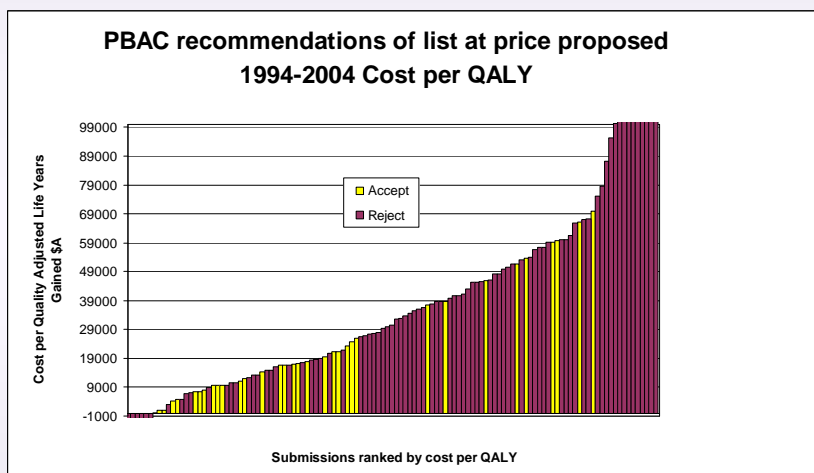
## PBAC recommendations

- **Recommend:**
  - Cost-minimisation (no price advantage)
  - Acceptable cost-effectiveness (price advantage)
  - Other factors (eg, rule of rescue)
- **Reject**
  - Incremental cost-effectiveness ratio unacceptably high
  - Poor quality of evidence
  - High level of uncertainty
  - Concerns about total cost
  - Concerns about leakage
  - Other concerns
- **Deferral**

## Relevant factors in PBAC decisions

- **Quantifiable**
  - comparative health gain
  - comparative cost effectiveness
  - total cost to government
  - affordability
  - financial implications for PBS
  - financial implications for government
- **Less readily quantifiable**
  - severity of condition treated
  - presence of effective alternatives
  - ability to target therapy to those likely to benefit most
  - non-health related benefits
  - uncertainty
  - equity
  - development of resistance

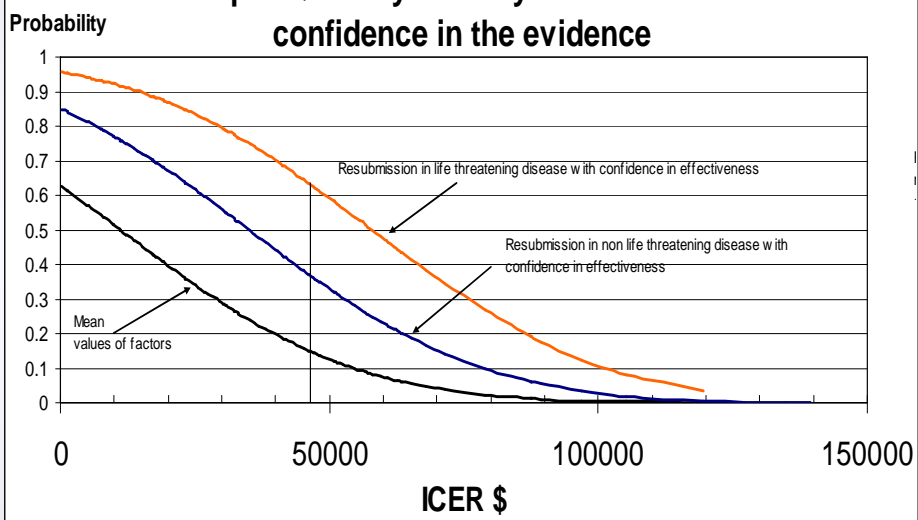
Descriptive data on decision to list drug on PBS and cost per QALY (uncontrolled for other factors)



Source: Harris, Hill, Chin, Li, Walkom (2007) The role of value for money in public insurance coverage decisions for drugs in Australia. A retrospective analysis 1994-2004c



Prob. of PBAC recommendation by incremental cost per QALY by severity of condition and confidence in the evidence



Source: Harris, Hill, Chin, Li, Walkom (2007) The role of value for money in public insurance coverage decisions for drugs in Australia. A retrospective analysis 1994-2004c



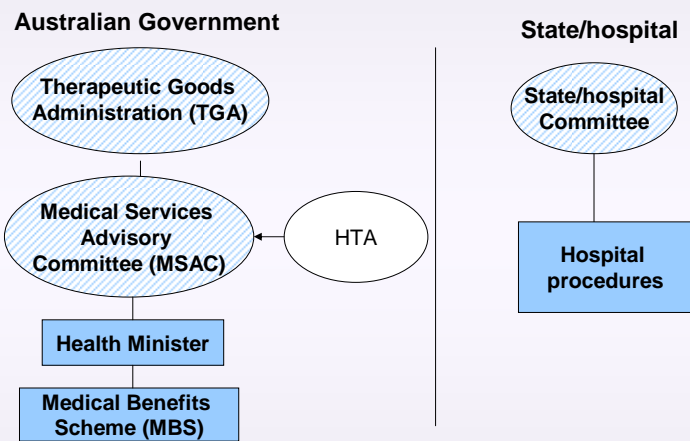
## Transparency of the PBAC

- A difficult issue
  - Submissions are commercial-in-confidence
  - Evaluation documents are commercial-in-confidence
- Decisions published on the Web
  - Both positive and negative
- Public summary documents made available
  - 14 weeks after decision
  - <http://www.health.gov.au/internet/main/publishing.nsf/Content/pbac-outcomes-and-public-summary-documents>

## Medical Services Advisory Committee

- MSAC provides recommendations to the Australian Minister for Health and Ageing regarding evidence relating to:
  - Safety
  - Effectiveness
  - Cost-effectiveness
  - Budgetary impact
- MSAC recommendations are used to decide whether public funding, via MBS is granted
  - Directly – MBS fee payable to medical practitioner
  - Indirectly – determines other costs associated with procedure e.g. theatre, bed-days, equipment and prosthesis

## The place of MSAC



## MSAC composition

- 3 Executive members
  - 1 chair
  - 2 deputy chairs
- 17 Members (mainly specialists), consumer representative (CHF), health economists (2), epidemiologist
- Recently introduced economics sub-committee

## Current MSAC process

- \$250,000 per application
- Slow appraisal process - up to 2 years
  - Creating an advisory panel
  - Balance b/w clinician engagement – process consultation and timely process
  - Balance between evidence and expert opinion
- Standard treatment not always an MBS listed item
- Evidence of Effectiveness
  - Not nearly as robust data as presented to PBAC
  - Sponsor often has markedly less funds to invest in studies generating high level data
  - Culture of surgical innovations historically occurring behind “closed doors”

## MSAC - Uptake and diffusion

- Established or intermediate technologies, but not “cutting edge technologies.”
- Technological imperative
  - Once MBS listed the cap is loose - strong economic incentives to use a technology once capital equipment is paid for, marginal cost is very low
- Incentive for the over provision of expensive technologies
  - Financial reward for doctors in a fee for service system
  - Facilitator of the uptake of new technologies **not** primary driver

## Challenges for MSAC

- Clarify role of advisory committee
  - Needs to be more advisory, not make recommendations
  - AC provides technical advice; advice reviewed by ESC; advice comes to MSAC, who make decision
- Cost-effectiveness evaluation compromised
  - MBS sets floor price + safety net = no ceiling
    - Price in CEA **not** what patient pays (dr's fees)
    - Price in CEA **not** what govt pays (safety net)

## Procedural fairness -1

- Daniels et al, ...”deliberate process is transparent and encourages relevant stakeholders to deliberate on relevant reasons as well as providing room for revising decisions”.
- MSAC process is generally fair and transparent, and has been increasingly so over time
- Minutes are published and made publicly available, draft reports are sent to applicants for critiquing.
- Reports are available on the website
  - <http://www.msac.gov.au/>

## Procedural fairness -2

- Decision making process is not consistent
  - Unlike PBAC – less looking back to previous decisions to see whether or not they are consistent
  - No consistent evidence across the reports
    - not using the same evidence, not using the same outcome measures, costed differently, across technologies (diagnostics, devices)
- Ultimately decisions are value judgements
  - other considerations in MSAC reports

## Summary

### PBAC

- Companies conduct research; PBAC commissions evaluations
- COI more readily avoided
- Cost-effectiveness
- Gate keeper re access

### MSAC

- MSAC-appointed group conducts evaluation
- COI difficult – need experts for process; they also stand to gain from decision
- Cost-effectiveness
- About price, not access