
“Options for the future of the PBS”

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Chair of PBAC

History

Repatriation Scheme Commenced in
1919

Pharmaceutical Benefits Act Passed
in 1944

History

- In the 1944 Act it stated that a person "shall not be disqualified from receiving any pharmaceutical benefit by reason of his sickness having been caused by his own misconduct"

History

- The 1944 Act was opposed by the Australian Branch of the BMA
- BMA saw the provisions of the Act as restricting doctors' freedom of choice in the treatment of their patients

History

- October 1945 ,as a result of a writ from the Medical Society of Victoria,the High Court ruled the PBA 1944 went beyond the powers of the constitution
- 1946 Constitution amended

NATIONAL MEDICINES POLICY

- Timely access to the medicines the Australians need ,at a cost individuals and the community can afford
- Medicines meeting appropriate standards of quality,safety and efficacy
- Quality use of medicines
- Maintenance of a responsible and viable medicines industry

NATIONAL MEDICINES POLICY

- In attempting to balance health needs and responsible fiscal discipline, the partners need to address the following issues

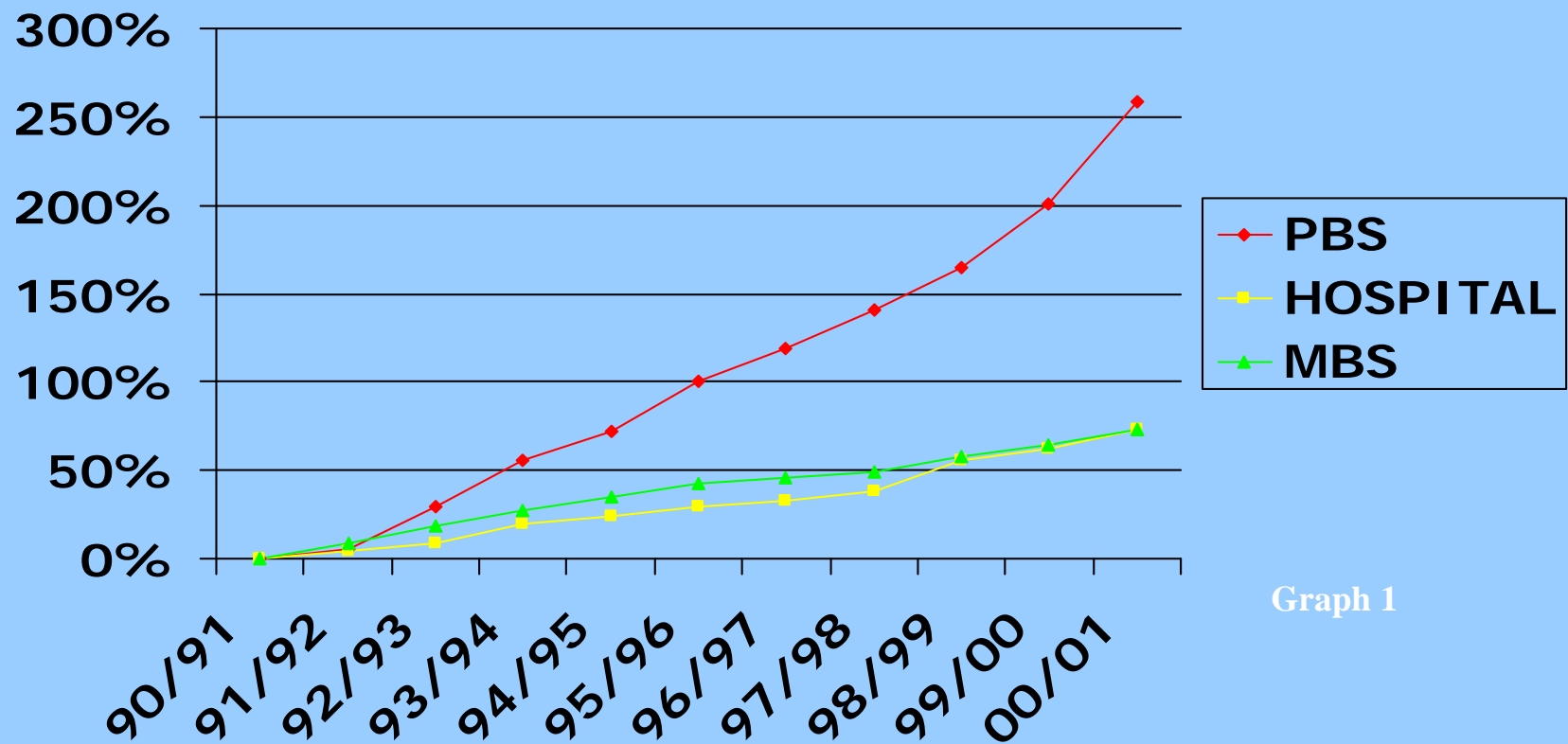
Access to Medicines-NMP

- Financing and supply arrangements for medicines optimise health outcomes and represent value for money
- All partners take adequate responsibility for achieving value for money
- Access to necessary medicines occurs at a cost the community as a whole can afford, particularly in the context of pressures such as the development of new high cost drugs and Australia's ageing population

Access to Medicines-NMP

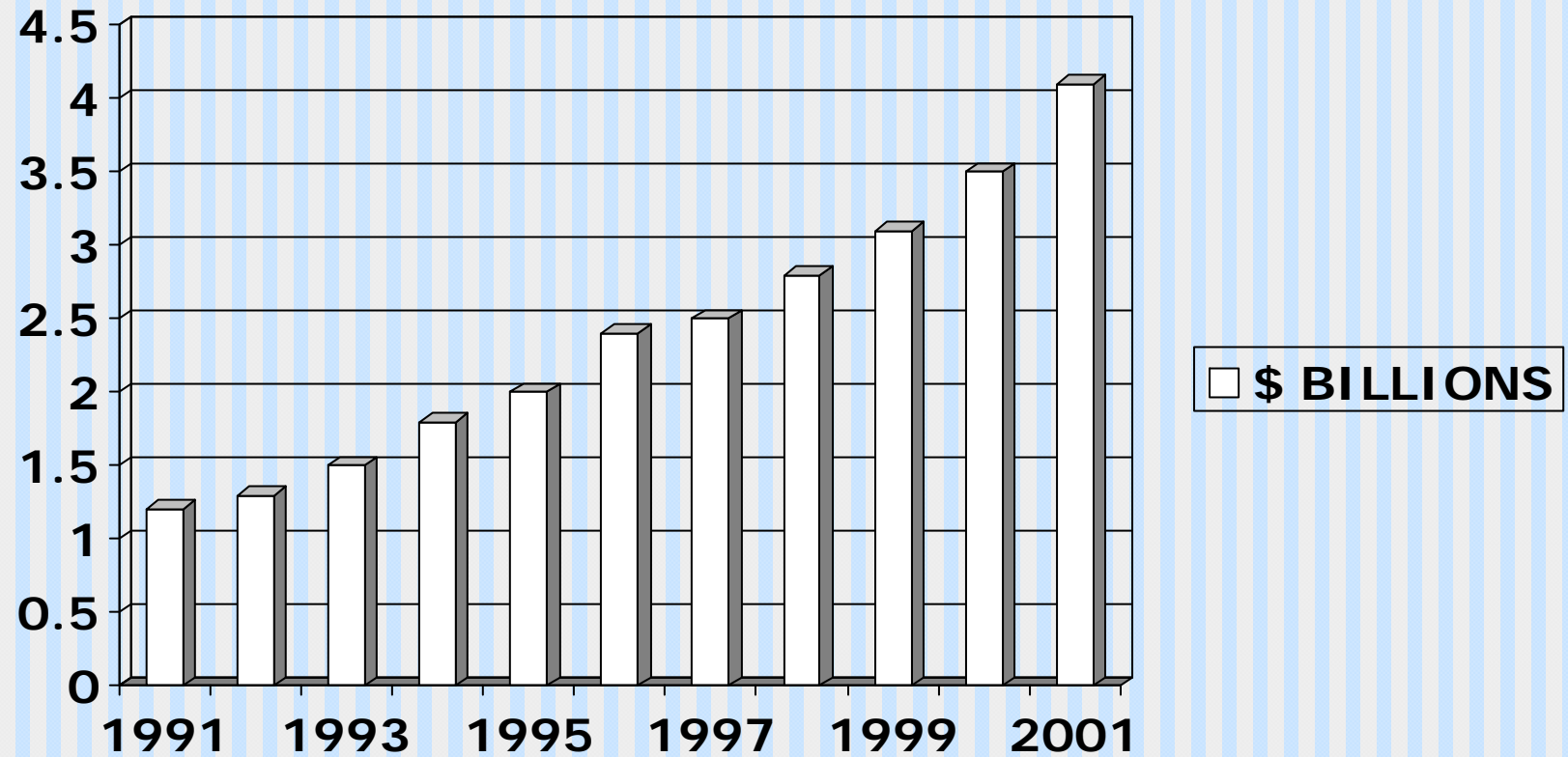
- Access processes are made as simple and streamlined as possible, so that subsidisation of medicines is timely, mechanisms are understood and unnecessary administrative barriers and expenses avoided
- Financing arrangements for medicines avoid incentives for cost-shifting between levels of government or other funders, or other perverse incentives

Cmwlth PBS, public hospital & MBS expenditure: % growth since 90/91

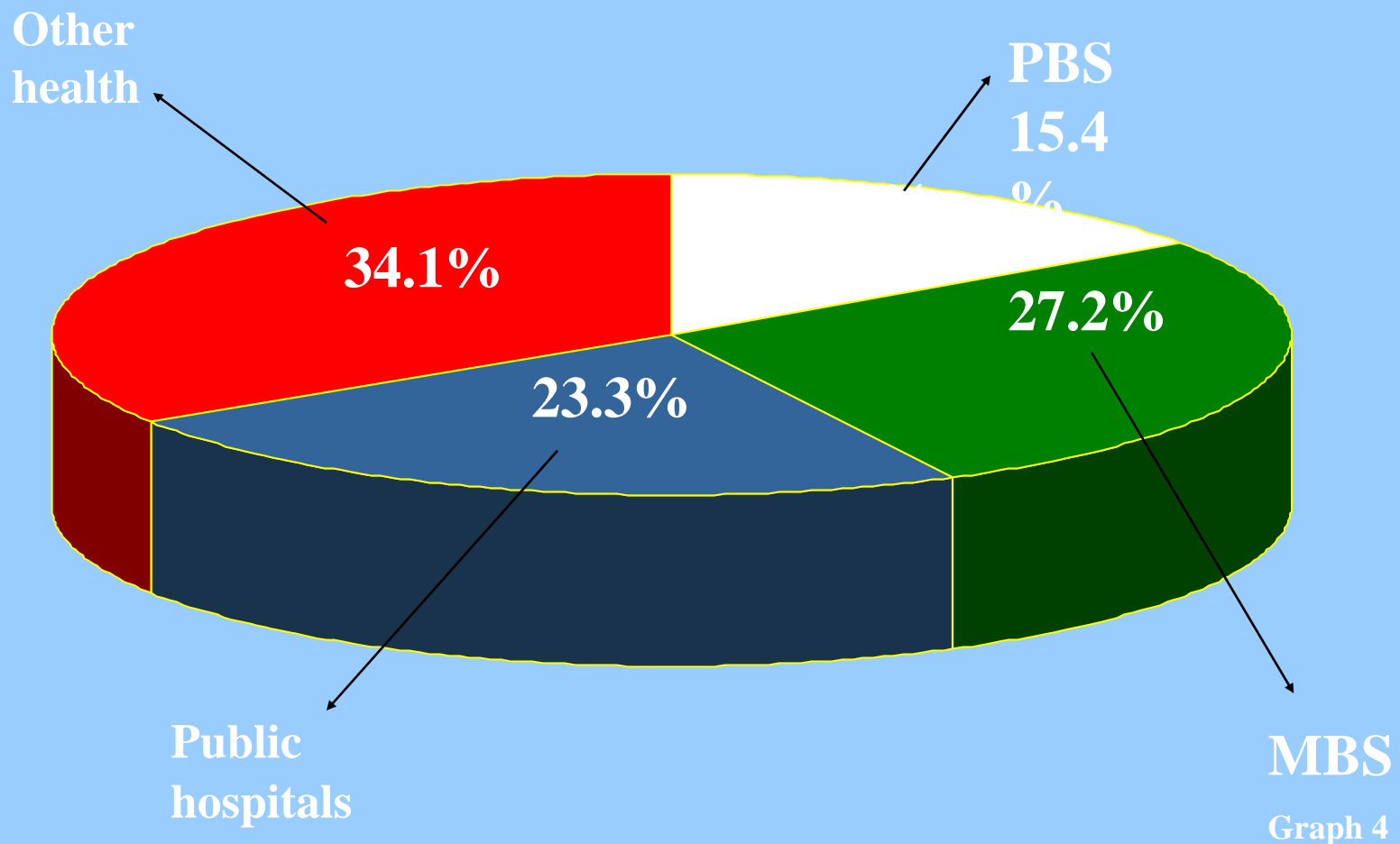


Graph 1

Present-GROWTH RATE IN PBS



Commonwealth Health Expenditure (\$27bn) 2000-2001



Graph 4

PHARMACEUTICAL EXPENDITURE

- 80% OF THE COST WAS DIRECTED TOWARDS CONCESSIONAL CARDHOLDERS
- PATIENT CONTRIBUTIONS AS A % OF TOTAL COST WAS 19.5% IN 90/91, 22.2% IN 94/95 AND 17% IN 01/02

Present-TGA APPROVAL

- PRODUCTS REGISTERED ON THE BASIS OF SAFETY, QUALITY AND EFFICACY.
- NO REQUIREMENT FOR COMPARATIVE DATA
- ONCE REGISTERED THE PRODUCT MAY BE PRESCRIBED WITHOUT GOVERNMENT SUBSIDY

Present-ASSESSMENT OF EVIDENCE

- SPONSOR ASKED TO CATEGORISE AGAINST THE MAIN COMPARATOR
- HAVING SIGNIFICANT CLINICAL ADVANTAGES
- BEING NO WORSE IN EFFECTIVENESS AND TOXICITY
- BEING LESS EFFECTIVE AND LESS TOXIC

PBAC PROCESSES

- PBAC considers effectiveness, cost effectiveness and the clinical place of the product compared to other products (or standard medical care) already listed (or used) for the same or similar indications

PBAC PROCESSES

- A new drug entity may be recommended for listing if
 - It is needed for the prevention or treatment of significant medical conditions not already, or inadequately covered by drugs in the existing list AND IS OF ACCEPTABLE COST EFFECTIVENESS

ECONOMIC EVALUATION

- **COST-MINIMIZATION....** Used when drugs have the same outcome. Ensure that the new drug is no worse than comparator ie therapeutic equivalence
- **COST EFFECTIVENESS....** Clinical advantage measured in natural unit ,eg life-years gained, points of BP reduction ie cost per unit of effect

ECONOMIC EVALUATION

- COST-UTILITY analysis-health outcomes rated by preference strength eg healthy years or quality adjusted life years (QALY). Output is cost per unit of preference state.
- MODELLED ECONOMIC EVALUATION...estimation of remote outcomes, final outcome, cost offsets

Present-RESTRICTIONS

- A DRUG MAY BE ACCEPTABLY COST EFFECTIVE WHEN USED FOR ONE INDICATION OR PATIENT GROUP BUT NOT COST EFFECTIVE WHEN USED UNDER OTHER CIRCUMSTANCES.

Present-PRICING AND COST CONTAINMENT

- BRAND PREMIUM POLICY AND GENERIC SUBSTITUTION
- THERAPEUTIC GROUP PREMIUM POLICY
- PRICE AVERAGING ACROSS INDICATIONS
- WEIGHTED AVERAGE MONTHLY TREATMENT COST
- PRICE VOLUME ARRANGEMENTS

Present-PBAC RECOMMENDATIONS

- LIST AS COST-EFFECTIVE AT PRICE PREMIUM REQUESTED
- LIST AT A LOWER PRICE TO ACHIEVE ACCEPTABLE COST EFFECTIVENESS
- REJECT AS HAVING UNACCEPTABLE COST-EFFECTIVENESS
- RESTRICT TO PATIENT SUBGROUPS IN WHOM THE DRUG IS COST EFFECTIVE

RELEVANT FACTORS

- ***Readily Quantifiable***

Comparative Cost Effectiveness

Comparative Health Gain

Affordability

Financial implications for PBS

Financial implications for Gov health budget

RELEVANT FACTORS

- ***Less Readily Quantifiable***

- Severity of condition treated

- Presence of effective alternatives

- Ability to target therapy to those likely to benefit most

- Uncertainty

- Equity

- Development of resistance

- Government health priorities and other relevant factors

FUTURE

- Demand for health services, including pharmaceuticals will continue to increase...“The demand for health services is insatiable”
- Aging population-more demand and lesser capacity to pay

Future

- New agents available as a result of the human genome project--new targets,
- Much greater attention to intellectual property issues
- Incremental improvements in treatment of malignancies, neurological disorders etc

Future

- High cost for drugs- many of them giving a relatively small incremental improvement resulting in what could be regarded as poor cost effectiveness
- Due to rapid expansion of knowledge it is unlikely that a patent life of 20+ years will be relevant

Future

- Increasing pressure on the “globalisation concept” of pharmaceuticals as illustrated by recent action in Africa and South America in regard to HIV drugs and in the US itself
- Growing inability of the developing world to afford new drugs

Future

- Growing accountability to ensure government expenditure is "value for money"
- Difficult decisions by society as to whether prioritisation of medicines expenditure is appropriate for certain conditions

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- Greater discussion on the cost of pharmaceuticals- significant efficiency gains in drug discovery by industry over the past decade

SPECIFIC ISSUES

TRANSPARENCY

- NEED FOR
-fundamental right to know by ALL stakeholders
- HOW-issues of commercial-in-confidence

IN WHAT FORM-different audiences have special needs

- LINKAGE WITH NPS-educational component in a timely manner

PBAC-TGA Registration v's Subsidisation

- Compatibility of TGA approval and PBS listing
- Class effects eg statins-onus of proof?
- Wide use of drugs for conditions not approved by TGA eg CBZ and neurogenic pain, ATRAs for heart failure
- Approval for indications not considered as cost effective by PBAC –“LEAKAGE”

NEW AGENTS WITH LIMITED DATA

- More new drugs receiving marketing approval with limited data-
- Uncertainty in the model used to predict benefit eg prolongation of life based on unsubstantiated assumptions. Increasing uncertainty in magnitude of benefit and thus in CE
- Need to develop risk sharing arrangements and regular review(not just of utilisation) of new listings eg at 1,2 and 5 years

“LEAKAGE”

- Prefer the term “Use outside approved subsidised indications”.
- Magnitude unknown-but likely to be significant
- Need to identify reasons-
intention(fraud),lack of appropriate education,marketing,emotive media reports etc-and initiate appropriate remedial action

TRIAL OUTCOMES v's IN-PRACTICE OUTCOMES

- Essential to ensure that successful outcomes in trials can be replicated in practice eg Bupropion-in the listing it is stated "For use within a comprehensive treatment program", but no requirement for the patient to participate or even enrol in a suitable program.

RESTRICTED LISTINGS

- Cost effective in one indication and not others.
- Last-line use requested as a justification for higher price and the use of placebo as comparator-but risk of leakage to first line setting. Drug may offer some advantages as first line but not at price offered

RESTRICTED LISTINGS

- Most prescribers do not read “yellow book” for restrictions but no supportive information provided-
NEED TO PROVIDE REASONS FOR RESTRICTION AT THE TIME OF LISTING AND SUITABLE ALTERNATIVE APPROACHES-use of NPS ,TGL, appropriate software

RESTRICTED LISTINGS

- Need to maintain a firm policy of risk sharing with respect to predicted use in excess of prediction ie price –volume agreements.
- Need to improve predictions of use at the time of listing-new role for DUSC
- Differential pricing/funding arrangements for categories of patients with different risk profiles.

COMMITTEE STRUCTURE

- Statutory Advisory Committee or Statutory Authority?

Recent suggestion for an Authority not required to work within a budget with the ultimate decision remaining with Government-no different from now except with the removal of the PBPA.

CURRENT PBAC ACTIVITIES

- Transparency-publication of reasons for decisions
- Review of COX-2s
- Examination of the restriction listings and release reasons for restrictions
- Linkage with NPS for educational initiatives

CURRENT PBAC ACTIVITIES

- Strengthen evidence-based approach to evaluation
- Examine QUM issues as part of the evaluation process
- Enhancement of the public awareness of the PBS and its processes

Future-necessity

- To facilitate change management, removal of any adversarial approach to interactions between the stakeholders while acknowledging there will be conflicts between them
- Develop an transparent framework in which PBAC can operate.

Future -necessity

- Greater commitment to the National Medicines Policy and recognition of the need to integrate the 4 arms
- Greater emphasis on the Quality Use of Medicines
- Comprehensive utilisation data linked to health outcome data

Future-necessity

- Recognition of the potential conflicts between social, economic, health and industry policies and the need for development of a “whole of government” approach
- Evidence-based decision making processes must be maintained
- Justification of the large cost of new drugs needed

Future-necessity

- Greater involvement of all stakeholders in the debate on future sustainability of the PBS