

澳洲PBAC組織的簡介

洪在華

2007/12/07

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大綱

- 沿革
- PBAC (Pharmaceutical Benefits Advisory Committee)的組織與運作
- PBPA (Pharmaceutical Benefits Pricing Authority)的組織與運作

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沿革



- 1944 澳洲國會通過Pharmaceutical Benefits Act – a person “shall” not be disqualified from receiving any pharmaceutical benefit by reason of his sickness having been caused by his own misconduct，要提供澳洲民眾有可以使用藥品的醫療照護的環境
- 1946 修憲，使得聯邦政府可以實施全國性藥品補助計畫
- 1954.05.12 PBAC正式成立，主要是依據National Health Act 內容，建立一獨立之組織，評估那些藥品及劑量是被視為需要有藥品補助的，並且針對其他有關之藥品補助計畫(PBS, Pharmaceutical Benefit Scheme)事項提出建議
- In 1987, the National Health Act 修法，要求PBAC在做建議時，應納入成本效益(cost-effectiveness)之考量

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沿革



- In 1990, PBAC 的作法是比較新藥與現有藥品的效益 (effectiveness)，以及安全性的差異
- In 1993, National Health Act 修改，要求PBAC 必須評估新藥與替代藥品(alternative therapies) 間的成本效益(cost effectiveness) 分析結果
- In 2002, 訂定” Guidelines for the pharmaceutical industry on preparation of submissions to the PBAC”
- In 2006, 除了修訂” Guidelines for the pharmaceutical industry on preparation of submissions to the PBAC” 外，為了使整個審核的process更透明，在2006，5月，訂定了” Policies, procedures and methods used in the pricing of pharmaceutical products”
⇒PBAC的網站可以找到每次開會的結果，最近的一次是July 2007 PBAC outcomes

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Basic Principles of PBS



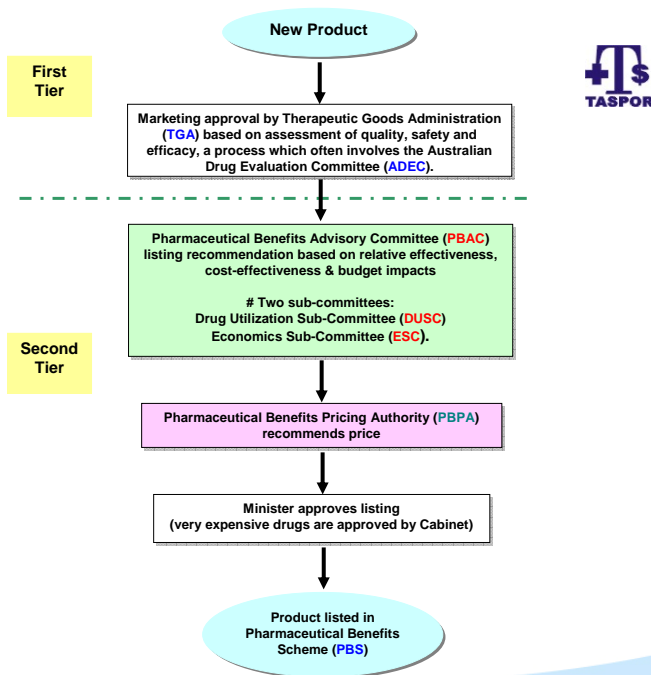
- The Minister may declare a drug listed on the PBS, but only after the **Therapeutic Goods Administration (TGA)** approval and under s101(4) after the **Pharmaceutical Benefits Advisory Committee (PBAC)** recommends it.
- The **Pharmaceutical Benefits Pricing Authority (PBPA)** negotiates price with manufacturer.

Part VII section 85 of the National Health Act 1953

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Market Access Process



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The Pharmaceutical Benefits Advisory Committee (PBAC)



- An independent expert body whose membership includes doctors, other health professionals and a consumer representative, recommends new drugs to be listed.
- Role :
 - Recommends drugs and medicinal preparations to the Minister for Health for funding under the Pharmaceutical Benefits Scheme (PBS).
 - Recommends vaccines for funding under the National Immunisation Program (since 2006).
 - Advises the minister and the Pharmaceutical Benefits Pricing Authority about cost-effectiveness ('value for money').
 - Recommends maximum quantities and repeats on the basis of community use, and any restrictions on the indications where PBS subsidy is available.
 - Regularly reviews the list of PBS items.
 - Advises the minister about any other matters relating to the PBS.

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PBAC 給衛生主管機關的建議



- 根據成本效益之分析可依據所要求之藥價給予給付
- 應該要降低藥品價格以使得成本效益分析之結果合理
- 由於所得之成本效益分析之結果並無法被接受，所以予以退件。
- 限制某些族群的病患可以使用，因為對於此一族群藥品是符合經濟價值。

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What data do the PBAC receive?



- Sponsor's submission
- PBAC secretariat overview
- Executive summary from submission
- ADEC minutes
- TGA delegate's summary
- PES (Pharmaceutical Evaluation Section)/DUSC secretariat evaluations
- Pre-subcommittee responses by the sponsor
- Advice from ESC, DUSC and RWG (Restriction Working Group)
- Pre-PBAC response by sponsor
- Product Information document
- Data on PBS listing of related drugs

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Sub-committee under PBAC



PBAC底下有兩個主要的sub-committee

- ESC (Economics sub-committee)
- DUSC (Drug Utilization sub-committee)

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Economics Sub-Committee (ESC) of the PBAC



- The Pharmaceutical Benefits Advisory Committee (PBAC) established the ESC in December 1993 under section 101A of the National Health Act 1953 to:
 - review and interpret economic analyses of drugs submitted to the PBAC;
 - advise the PBAC on these analyses; and to
 - advise the PBAC on technical aspects of requiring and using economic evaluations.

PS: The members include clinicians, clinical epidemiologists, health economists, biostatisticians and clinical pharmacologists. As part of its terms of reference, ESC is also responsible for revisions of the guidelines

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Drug Utilisation Sub-Committee (DUSC) of the PBAC



- The Pharmaceutical Benefits Advisory Committee (PBAC) established the DUSC in 1988 under section 101A of the National Health Act 1953 to:
 - collect and analyse data on drug utilisation in Australia for use by the PBAC;
 - make inter country comparisons of drug utilisation statistics; and to
 - assist in generating information relating to rational use and prescribing of medicines.
 - **Budget Impact Evaluation**

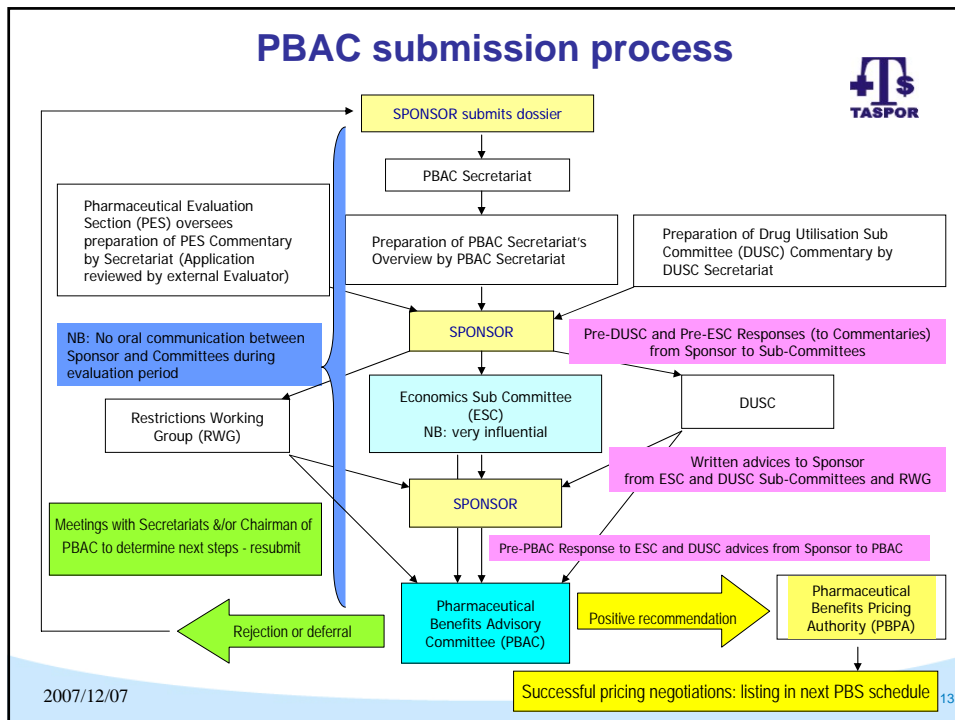
The DUSC secretariat is responsible for publishing the Australian Statistics on Medicines on an annual basis.

PS: The members have a broad range of relevant expertise and mainly come from organisations interested in the evaluation of drug utilisation.

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PBAC submission process



Conduct of PBAC meeting



- Two discussants (reviewers) for each item
- First discussant summarises submission and ends with draft decision
- Usually by reference to ESC advice
- Second discussant agrees or adds
- Agenda item open for general discussion
- Formal vote taken, if necessary
- Companies also have an opportunity to present to the committee for 10 minutes

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How are products listed on PBS?



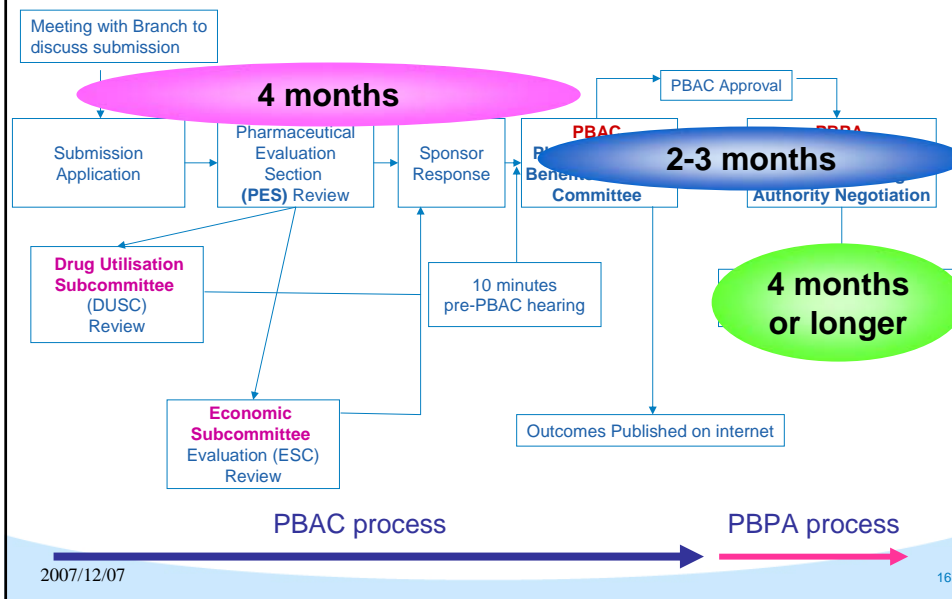
- Major submissions
 - Executive Summary
 - Section A, (requested listing)
 - Section B, (key clinical evidence)
 - Section C, (translation of evidence to requested listing)
 - Section D, (economic analysis)
 - Section E, (financial implications)
 - Section F, (other important factors e.g. QUM)
- Minor submissions
 - e.g. new formulation, new brand or change in restriction
 - No specific format
 - Economic evaluation not required
 - Not usually reviewed by PBAC subcommittees
 - Deadline approx. 6 weeks after major submissions

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The Reimbursement Process (major submissions)

The existing reimbursement process is complex and lengthy



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Table: Timeline of PBAC procedures



Action or event	Time relative to PBAC meeting
• TGA delegate's overview/advice to ADEC and/or ADEC resolution and/or TGA registration granted	
• Cut-off date for major submissions to department	17 weeks before
• Cut-off date for minor submissions to department	11 weeks before
• Departmental papers to sponsors	6 weeks before
• Sponsor's pre-subcommittee response to department	5 weeks before
• Meeting of subcommittees	4 weeks before
• Subcommittee papers to sponsors	2 weeks before
• Sponsor's pre-PBAC response to department	1 week before
• PBAC meeting	
• Verbal advice to sponsor	half a week after
• Written advice to sponsor	3 weeks after
• Publication of PBAC outcomes on departmental website	6 weeks after
• PBAC ratified minutes to sponsor	10 weeks after
• Publication of public summary document on departmental website	16 weeks after
• Publication of public summary document (first time rejections)	18 weeks after

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Version 4.1 (Dec. 2006)

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After PBAC meeting



- 依據2006年5月訂定的” Policies, procedures and methods used in the pricing of pharmaceutical products” ，PBAC會把每次開會的結果，列屬positive recommendation的案子放在網站上
- 最近的一次是July 2007 PBAC outcomes，有39個案子列屬positive recommendation，其中major submission有10例， minor submission有29例

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After positive PBAC recommendation

- **Pharmaceutical Benefits Pricing Authority (PBPA)** will review proposed listing (population, price)
- Items presented with draft recommendation and reasons, PBPA may/may not agree. A different price may be proposed.
- Risk share arrangements common where uncertainty over PBS cost and Deed of Agreement will be developed
- Cabinet approval required for PBS costs >\$10m (around NTD276m) (exchange rate 1 Aus ~ 26.7 NTD)

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The Pharmaceutical Benefits Pricing Authority (PBPA)

- An independent non-statutory body, established on 1st Jan., 1988
- PBPA成立的目的是向納稅人及使用者確保藥品的供應面，及列入藥品給付之品項，其價格是合理的，而且並須與維持澳洲藥業永續的、負責任的政策是一致的。

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The Pharmaceutical Benefits Pricing Authority (PBPA)



- Role :
 - To review the prices of products supplied under the Pharmaceutical Benefits Scheme (PBS)
 - To recommend prices for new items are recommended for listing on the PBS

For pricing reviews, the Pricing Authority currently meets three times per year, in line with the three meetings per year of the PBAC. PBAC meetings are held in March, July and November, PBPA meetings are held in April, August and December.

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Factors considered by the PBPA



- ✓ PBPA comments on clinical and cost effectiveness aspects of items
- ✓ The prices of alternative brands of a drug
- ✓ Comparative prices of drugs in the same therapeutic group
- ✓ Costs information, when provided by the supplier of estimated by the PBPA
- ✓ Prescription volumes, economics of scale and other factors such as expiry dating, storage requirements, product stability and special manufacturing requirements;
- ✓ Level of activity being undertaken by the company in Australia, including new investment, production, research and development;
- ✓ Prices of the drug in reasonably comparable overseas countries;
- ✓ Other relevant factors which the applicant company may wish the PBPA to consider; and
- ✓ Any directions of the Minister

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Estimated extent of use and financial implications

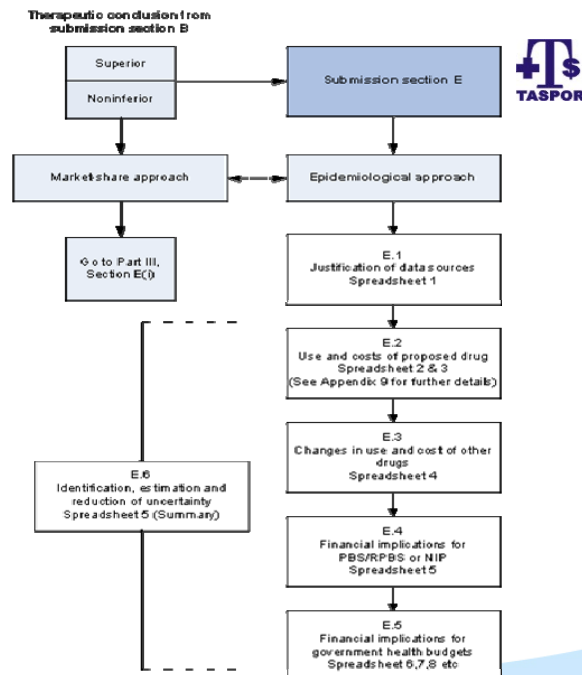


- Justification of the selection of sources of data
- Estimation of use and costs of the proposed drug
 - Estimate the number of patients with the medical condition targeted by the proposed drug, the number who would be eligible for the requested restriction and the number of patients likely to take the proposed drug.
- Estimation of changes in use and cost of other drugs
 - Drugs likely to be affected by the listing of the proposed drug
- Estimated financial implications for the PBS/RPBS or the NIP
 - Estimate the net financial implications for the PBS and the RPBS (or the NIP) in each year over five years
- Estimated financial implications for government health budgets
- Identification, estimation and reduction of uncertainty

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Key information requests for budget impact



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Budget Impact Analysis



$$f(x) - f(y) + f(x') - f(y')$$

x : incremental drug cost of the proposed item

y : drug cost replaced by the proposed item
(the proposed item vs competitors)

x' : incremental cost caused by managing major side effects, concomitant or preventive medicines of the proposed item

y' : cost saved due to *managing major side effects, concomitant or preventive medicines of the competitors*

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Categories of data sources



Disease epidemiological data (provide estimates of prevalence or incidence in the population)
<ul style="list-style-type: none"> •Australian case or mortality registers estimate the incidence or prevalence of a disease •Large, well-designed Australian studies estimate the incidence or prevalence of a disease •Australian national health surveys estimate the prevalence of a disease
Pharmacoepidemiological data (provide estimates of treated prevalence)
<ul style="list-style-type: none"> •Surveys of the treated prevalence of the disease in Australia •Studies using utilisation databases, including PBS/RPBS data
Market data
<ul style="list-style-type: none"> •Quantitatively describe the existing market •Estimate relative market shares •Estimate the impact of the requested PBS listing on current treatment paradigms based on similar previous listings.

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