Chapter 2

Pharmaceutical Benefits Scheme

The Authority's objective in reviewing prices of items listed under the Pharmaceutical Benefits Scheme is to secure a reliable supply of pharmaceutical products at the most reasonable cost to Australian taxpayers and consumers and consistent with maintaining a sustainable pharmaceutical industry in Australia..

Under its terms of reference the Authority is required to determine or recommend to the Minister for Health and Family Services prices of items listed as pharmaceutical benefits or recommended by the Pharmaceutical Benefits Advisory Committee for listing. It also conducts negotiations with suppliers, where necessary, on proposed prices.

Factors considered by the Authority

In reviewing the price of listed items and in considering the price of items recommended for listing, the Authority takes account of the following factors:

(a) Pharmaceutical Benefits Advisory Committee comments on clinical and cost effectiveness aspects of items;

(b) the prices of alternative brands of a drug;

(c) comparative prices of drugs in the same therapeutic group;

(d) costs information, when provided by the supplier or estimated by the Authority;

(e) prescription volumes, economies of scale and other factors such as expiry dating, storage requirements, product stability and special manufacturing requirements;

(f) the level of activity being undertaken by the company in Australia, including new investment, production, research and development;

(g) prices of the drug in reasonably comparable overseas countries;

(h) other relevant factors which the applicant company may wish the Authority to consider; and

(i) any directions of the Minister.

The Authority takes into account factors (a) to (e), and (g) to (i) in undertaking its regular reviews of the price of listed items. Factor (f) is considered in the context of the Authority's activities under the Factor (f) Scheme which is part of the Pharmaceutical Industry Development Program dealt with in chapter 3 of this report.

Price adjustments for items which have an annual cost exceeding $200,000 require the approval of the Minister for Health and Family Services.

Establishing Prices for New Listings

For new listings recommended by the Pharmaceutical Benefits Advisory Committee and approved by the Minister, the Authority recommends prices to be negotiated by the Department of Health and Family Services.

New drugs, or new indications of an existing benefit, estimated to cost more than $10 million per annum require Cabinet approval prior to listing.

The main mechanism to determine initial prices is the advice of the PBAC arising from the cost effectiveness information supplied by the sponsor and evaluated by the PBAC.

In recent years, the PBPA has increasingly recommended the use of price/volume arrangements, particularly where unit prices are reasonably high and there is the potential for significant volumes or where there is uncertainty about future volumes. Such arrangements have also been negotiated where there is potential for volumes to increase due to easing of PBS restrictions and/or widening subsidised indications.

Reviewing prices for existing items

The main mechanisms used by the Authority for reviewing prices of pharmaceutical products supplied through the Pharmaceutical Benefits Scheme are:

- comparative prices of products that are considered by the Pharmaceutical Benefits Advisory Committee to have a similar therapeutic effect or benefit, or where this is not available;
- on the basis of further cost effectiveness justification by the sponsor;
- gross margin on the cost of manufacture, or landed cost; and
- a weighted average monthly treatment cost basis.

The Authority may also request additional data from applicants, including drug utilisation data, so that relevant treatment costs can be independently calculated.

Therapeutic Relativities

The Authority issues and distributes relativity sheets which identify the basis of pricing comparisons between therapeutically similar products. The industry is encouraged to comment on these relativities.

Effects of price adjustments

Prices or price adjustments determined or recommended by the Authority have an impact on:

- suppliers through adjusted selling prices;
- wholesalers through the margin on the agreed price of products to pharmacist;
- pharmacists through the mark-up on wholesale prices;
- hospitals dispensing highly specialised drugs to community based patients through the joint Commonwealth/State funding arrangements provided for under Section 100 of the National Health Act 1953; and
- consumers and taxpayers who, either directly or indirectly, bear part or all of the cost of the drugs dispensed under the Pharmaceutical Benefits Scheme.

The prices set by the Authority cover not only subsidised products, but also products listed in the Schedule priced below the maximum co-payment for general patients. This co-payment is currently $20.00.

Brand Pricing Policy

The Brand Pricing Policy was introduced in December 1990 to reduce price control where possible by allowing pharmaceutical suppliers to set their own prices on multi-branded and therapeutically interchangeable brands listed on the Pharmaceutical Benefits Scheme, provided one brand was available at the subsidised price. This also encourages the development of the generic pharmaceutical industry in Australia.

The policy for alternative brands has the effect of making it possible for prescribers and patients to be more aware of the price of drugs. The policy also allows companies to establish prices taking into account competition and the heightened consumer awareness of price differentials.

The policy operates where there is more than one brand of a particular drug available through the Pharmaceutical Benefits Scheme and where the brands are therapeutically interchangeable. The policy mainly applies, therefore, to out of patent drugs.

Under the policy, suppliers of multi-branded items are able to set their own prices at a level they think the market will bear. At the same time, prescribers, pharmacists and patients can decide whether it is necessary to pay more for a particular brand when a cheaper equivalent and therapeutically interchangeable brand is available.

Basically, the policy operates by:

- the Commonwealth subsidising a drug to the level of the lowest priced brand;
- suppliers of other brands of that drug being able to set a price above the price charged by the supplier of the lowest priced brand, where the brands are bio-equivalent; and
- the patient paying the brand premium which is the price difference between the lowest priced brand and the brand prescribed.

As the brand premium is not a Government charge, it does not count toward a patient's safety net. The premium arises from the supplier's price setting and the majority of it goes to the supplier, with wholesalers and pharmacists receiving a percentage.

As at 30 June 1998 there were 209 benefit items with a brand premium that could be therapeutically interchanged. The average brand premium was $1.60 and premiums ranged from 22 cents to $6.08. The majority of brand premiums were in the range of $1.00 to $1.50.

Brand Substitution

Brand substitution by pharmacists, which became effective from 1 December 1994, for certain items without reference back to the prescriber, gives patients a greater opportunity in deciding what they pay for their medication under the Minimum Pricing Policy.

Equivalent brands are shown in the Schedule of Pharmaceutical Benefits as having been demonstrated to be bio-equivalent or therapeutically equivalent, or that justification for not needing bio-equivalence or therapeutic equivalence data has been provided and accepted by the Therapeutic Goods Administration. If other brands are not shown in this way it does not imply that they are not equivalent, but simply that it is unknown whether or not they are equivalent.

The following table shows the effect of brand substitution.

	December 1994	PBS Schedule November 1997	PBS Schedule February 1998	PBS Schedule May 1998
Number of products with a premium	124	192	202	209
Average brand premium	$1.54	$1.64	$1.68	$1.60
Weighted average brand premium	$1.07	$1.23	$1.31	$1.31
Brand premium range	$0.19 to $11.26	$0.22 to $9.25	$0.22 to $9.25	$0.22 to $6.08
Prescriptions dispensed with a brand premium in the previous 12 months	26.0m	30.6m	32.9m	33.9m
Prescriptions dispensed at the benchmark level in the previous 12 month period	5.4m	13.4m	15.5m	15.7m
Percentage of prescriptions at the benchmark level	17%	31%	32%	32%

Weighted average brand premium is calculated by:

scripts x premium = total premium value,
total premium value/total scripts = weighted average brand premium

Therapeutic Group Premium (TGP) Policy

In the 1997 Budget, the Government announced that it intended to extend the Brand Pricing Policy where price premiums apply to individual bio-equivalent brands of a drug to groups of drugs which have similar clinical activity (reference pricing).

Six drug groups were initially proposed as being under the TGP policy. These were: ACE Inhibitors, Calcium Channel Blockers and Beta Blockers, all used to treat cardiovascular disease, Selective Serotonin Re-uptake Inhibitors (SSRI's) used to treat depression, HMG CoA reductase inhibitors used for lowering blood cholesterol and the H2 receptor antagonists for the treatment of peptic ulcers. Based on expert technical advice, the Government decided to remove two groups, Beta Blockers and SSRI's, from the TGP policy.

The new arrangements were implemented with effect from 1 February 1998. The Government subsidy is based on the benchmark price (ie. the lowest priced drug/s in each group) and the price difference for a more expensive drug within the relevant group is paid by the patient over and above the relevant patient co-payment.

Under the TGP policy where a patient cannot for clinical or compliance reasons tolerate the benchmark priced drug, the prescriber can apply to the Health Insurance Commission for an exemption to supply the dearer alternative drug at no extra cost to the patient.

A public education campaign, incorporating a help-line service, has been put in place to raise awareness of the policy and generate an increased cost-consciousness among consumers and health professionals.

The prices of items in the four therapeutic groups under the TGP are reviewed by the PBPA on a weighted average monthly treatment cost basis.

As at 30 June 1998 there were 71 items within the four groups under the TGP policy. These consisted of 105 brands at the benchmark price, 17 brands with a brand premium and 29 with a therapeutic premium. There were also three strengths of a drug which has one brand that has both a TGP and a brand premium. The TGP's ranged from $0.70 to $4.46.

Cost Authority

Drugs may be listed in the Pharmaceutical Benefits Scheme under "cost authority". This occurs when the weighted average monthly treatment cost of a drug exceeds $32.75 and there is a suitable cheaper alternative available.

Consideration was given to the removal of the cost authority during the year, but the Government decided that the cost authority should remain for the time being.

The application of cost effectiveness has tended to obviate the need for the cost authority. New products listed on the PBS can be listed at a higher price than alternate products if it can be demonstrated that the additional clinical benefits represent value for money. Currently there are no products listed with a cost authority restriction.

Highly specialised drugs

Section 100 of the National Health Act, provides for an alternative means of providing an adequate pharmaceutical service in circumstances where pharmaceutical benefits cannot be conveniently and efficiently supplied as normal under the Pharmaceutical Benefits Scheme.

There are certain drugs which need to be restricted for supply through hospitals to community patients because the hospitals can provide the facilities or staff necessary for the appropriate use of the drugs. These drugs called Highly Specialised Drugs are among those supplied via Section 100. For Highly Specialised drugs the Commonwealth pays the drug cost for out-patients and the States pay, through the Medicare Agreement, for in-patient costs in public hospitals.

A working party established by the Australian Health Ministers' Advisory Council advises the Government, amongst other things, on the selection and monitoring of the highly specialised drugs.

For a drug to be approved under these arrangements and be included in the Scheme, it must comply with specific criteria agreed between the Commonwealth and the State/Territory Governments and be so recommended as a pharmaceutical benefit under Section 100 by the Pharmaceutical Benefits Advisory Committee.

If a drug is suitable for supply through the normal PBS arrangements, it is not eligible for funding through the Highly Specialised Drugs arrangements. The funding to the States, additional to the Medicare funding, is only available when the public hospitals are used as the necessary mode of supply to PBS patients.

Health Care Agreement

Under the Health Care Agreement between the States and Commonwealth for the funding of public hospitals, the Commonwealth has offered the States access to the PBS.

The offer was available from 1 July 1998, and if accepted by the States, permits access to the PBS for discharged patients or outpatients of the public hospitals. The hospitals are expected to meet accepted standards of pharmaceutical care.

The arrangements mean that there is similar equity of access to necessary medicines for community patients whether they use public hospitals or other facilities.

The criteria for selection of Highly Specialised Drugs is:

(i) Ongoing specialised medical supervision required

Ongoing specialist treatment should not preclude treatment in a community setting and should be interpreted to include specialist initiated treatment where ongoing treatment may be under the supervision of a community general practitioner but involve periodic reference to the specialist facility.

(ii) Treatment of longer term medical conditions not episodes of in-patient treatment or treatment of acute conditions.

The intent is to assist the ongoing maintenance of patients in the community setting. Treatment may include administration by other than the oral route and may occur in a day procedure setting including supervision by a community practitioner.

(iii) Drug highly specialised and an identifiable patient target group

This criterion is defined as relating to high cost drugs in respect of which a treatment regimen is associated with ongoing specialist supervision which normally occurs in an institutional setting.

(iv) Subject to marketing approval by the Therapeutic Goods Administration (TGA) and specific therapeutic indications covered by the terms of the marketing letter from TGA

From the Commonwealth's perspective the only avenue for funding any drug under the agreed arrangement is through the Pharmaceutical Benefits Scheme via section 100 involving endorsement by the Pharmaceutical Benefits Advisory Committee and meeting TGA specified marketing conditions.

(v) High unit cost

In this context high unit cost is interpreted as a cost beyond the normal financial capacity of individuals and imposing significant financial burden on specialised institutions.

The Authority's role in respect of these drugs, is to review and negotiate national prices for their supply. Prices are negotiated at ex-manufacturer level. The prices and prescribing restrictions for these highly specialised drugs are separately listed in the Schedule of Pharmaceutical Benefits.

At 30 June 1998 there were thirty highly specialised drugs listed under Section 100.

Special Patient Contribution

There are currently three products listed which have a special patient contribution. This occurs when a pricing agreement between the Government and supplier cannot be reached for unique products.

The special patient contribution is the difference between the dispensed price requested by the supplier and the Government's dispensed price. The special patient contribution is payable by all patients in addition to the relevant patient contribution for concessional and general patients.

Therapeutic Group Reviews

The Authority reviews annually the price of each drug listed in the Pharmaceutical Benefits Scheme by therapeutic groupings. In special circumstances, the Authority will accept applications from suppliers for ad-hoc pricing reviews. Suppliers are asked to submit cost and other data that they wish the Authority to consider in reviewing product prices.

Confidentiality of information

All information provided on a confidential basis to the Authority is strictly treated as such, and is not disclosed to any person apart from members of the Authority and relevant officers of the Department of Health and Family Services and the Department of Industry, Science and Tourism, without the express permission of the Chairman and the company concerned.

Results of therapeutic group reviews 1997-98

In the 1997-98 financial year, the Authority held four therapeutic group reviews, the summary results of which are compared below with those for the previous year:

Product review results	**1996-97**	**1997-98**
Number of products reviewed:	1,804	2,051
Number of products for which price applications were received:	467 25.9%	495 24.1%
Number of products for which price increases were granted:	180 10%	158 7.7%
Number of products for which price decreases were requested:	17 0.9%	28 1.4%

The number of new items recommended for listing and new items actually listed for the financial year 1997-98 was:

Number of items recommended for listing by the Pharmaceutical Benefits Advisory Committee (based on PBAC meetings held in 1997-98 financial year, includes different strengths)	:	100
Number of items listed (based on new items listed in the PBS Schedules for 1997-98)	:	104

Estimated cost of price increases of existing items 1997-98

The general price increases granted to suppliers in 1997-98 are collectively estimated to add $6.52 million to the cost of the Pharmaceutical Benefits Scheme in a full year based on the latest available twelve months prescription volume for each item at the time of review. A comparison with the estimated full year costs in the previous year is set out below:

Approval of price increases	**1996-97** $ million	**1997-98** $ million
Approved by Authority	0.49	0.20
Recommended by Authority and subsequently approved by the Minister	5.54	6.93
Total	6.03	7.13

These cost estimates do not include any expenditure for increased Australian activities considered under factor (f).

Cost of Pharmaceutical Benefits Scheme, 1997-98

The total cost of pharmaceutical benefits for 1997-98 was $3,112.3 million and comprised Commonwealth Government payments of $2,541.5 million and patient contributions of $570.8 million.

Category	Processed Script numbers	Cost to Govt (excludes patient contributions)	Total cost
	# million	$ million	$ million
General	14.1	411.9	693.6
General safety net	3.9	98.6	111.2
Concessional	86.4	1576.1	1,852.5
Concessional safety net	20.1	440.0	440.0
Miscellaneous Dr's Bag	0.6	15.0	15.0
Total	125.1	2,541.6	3,112.3

Note: For the general public, where a pharmaceutical benefit is priced below the general patient contribution (that is, $20.00), the consumer pays the full amount including an additional dispensing fee of 85 cents provided that the total cost does not exceed $20.00. The above figures do not include these amounts.