



Pharmaceutical Benefits Pricing Authority

Annual Report

for the year ended 30 June 1999



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For the year ended 30 June 1999

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ISBN 0642415226

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Publication approval number: 2605

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PBPA

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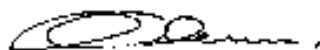
Senator The Hon. Grant Tambling MP
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Dear Parliamentary Secretary

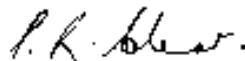
We present herewith the twelfth annual report of the Pharmaceutical Benefits Pricing Authority on the operations of the Authority, and on the Authority's interpretation of its operating guidelines for the year ended 30 June 1999.

This report is made in accordance with the requirement of sub-section 140(2) of the Acts Interpretation Act 1901, that in the absence of specific requirements to the contrary, an annual report shall be furnished to you as soon as practicable after the end of the reporting period.

Yours faithfully



Graham Glenn
Chairman



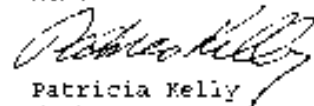
Pat Clear
Member



Geoff Hudson
Member



Brett Lennon
Member



Patricia Kelly
Member

7 September 1999

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Preface

This is the twelfth annual report of the Pharmaceutical Benefits Pricing Authority covering the operations of the Authority for the year ended 30 June 1999.

Tabling requirements

It is a requirement of sub section 34C(3) of the Acts Interpretation Act 1901, that in the absence of specific requirements to the contrary, the annual report shall be laid before each House of the Parliament within 15 sitting days of that House after the day on which the Minister receives the report.

Structure of report

The report is divided into four chapters:

- chapter 1 provides basic information about the Authority's genesis, membership and financial arrangements;
- chapter 2 addresses the factors considered by the Authority for pricing of pharmaceutical benefits made available under the Government's Pharmaceutical Benefits Scheme administered by the Department of Health and Aged Care;
- chapter 3 deals with activities under the Government's Pharmaceutical Industry Development Program administered by the Department of Industry, Science and Resources; and
- chapter 4 contains related tables and figures.

An appendix reprints the Factor (f) Pricing Guidelines issued in June 1992 for the guidance of pharmaceutical suppliers seeking price increases under the Factor (f) Scheme which concluded on 30 June 1999.

Chapter 1

Pharmaceutical Benefits Pricing Authority

The Pharmaceutical Benefits Pricing Authority is an independent non-statutory body established in 1988 which is required to:

- review the prices of products supplied under the Pharmaceutical Benefits Scheme;
- recommend prices for new items that are recommended for listing on the Pharmaceutical Benefits Scheme;
- assess suppliers proposals for inclusion in the Factor (f) Scheme of the Pharmaceutical Industry Development Program; and
- monitor the performance of suppliers approved for inclusion in the Factor (f) Scheme and from 1 July 1999 the Pharmaceutical Industry Investment Program.

Membership

The Authority's membership for the 1998-99 financial year was:

Chairman	Mr Graham Glenn—appointed with effect from 1 June 1992.
Industry nominee	Mr Pat Clear—appointed with effect from 27 September 1995, as the nominee of the Australian Pharmaceutical Manufacturers' Association.
Consumer nominee	Mr Robin Brown—appointed with effect from 22 November 1991 to 9 December 1998. Mr Geoff Honnor—appointed with effect from 10 December 1998 as the nominee of the Consumers' Health Forum.
Department of Health and Aged Care representative	Dr David Graham—appointed with effect from 18 May 1992 to 22 November 1998. Mr Brett Lennon—appointed with effect from 23 November 1998.
Department of Industry, Science and Resources representative	Ms Patricia Kelly—appointed with effect from 22 April 1998.

Secretariat support

The Authority is serviced by two secretariats, viz:

- PBS pricing matters
- Industry development matters

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The Authority supports best management practice in communicating with suppliers and other interested parties to make the Authority's decisions and decision making processes as transparent as possible, subject to the confidences in which certain commercially sensitive information must be held.

Consultation with respective secretariat staff on the interpretation of the Authority's guidelines, practices and procedures is encouraged to ensure that all interested parties gain a clear understanding of those matters and have the maximum opportunity to make their views known to the Authority.

Technical support

Technical advice to assist the Authority in its deliberations is provided by the Pharmaceutical Benefits Advisory Committee (PBAC). This includes information on drug relativities and their cost effectiveness provided by the PBAC's Economics Sub-committee.

Co-ordination to achieve timely outcomes

Pricing Authority meetings are carefully co-ordinated with meetings of the PBAC, so that PBAC outcomes can be dealt with as soon as possible consistent with the need to collect pricing information.

Financial arrangements

The Department of Health and Aged Care budget, in addition to financing the Pharmaceutical Benefits Scheme, provides funds for:

- the fees and expenses incurred by the Chairman, industry and consumer nominees, in accordance with determinations made from time to time by the Remuneration Tribunal;
- the day to day operations of dealing with pricing matters under the Scheme; and
- the costs of associated meetings, seminars and other related expenses.

The Department of Industry, Science and Resources budget, in addition to financing the Pharmaceutical Industry Development Program, provides funds for running costs associated with industry development matters under the Program, including the Factor (f) Scheme.

For the year ended 30 June 1999 the Authority operating costs were:

Authority operating costs 1998-99	Health portfolio	Industry portfolio	Total costs
	\$	\$	\$
Direct costs including Chairman's, industry and consumer nominees' expenses	19,856	1,930	21,786
Salaries	253,537	57,543	311,080
Members & secretariat travel and allowances	19,567	1,650	21,217
Administrative and property costs	202,830	56,100	258,930
Total costs	495,790	117,223	613,013

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 Aged Care 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 Aged Care.

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 Aged Care.

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 Authority 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 \$20.30.

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 1999 there were 226 benefit items with a brand premium that could be therapeutically interchanged. The average brand premium was \$1.80 and premiums ranged from \$0.23 cents to \$7.28. 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 Brand 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	August 1998	November 1998	February 1999	May 1999
Number of products with a premium	124	212	216	219	226
Average brand premium	\$1.54	\$1.63	\$1.70	\$1.72	\$1.80
Weighted average brand premium	\$1.07	\$1.31	\$1.36	\$1.39	\$1.44
Brand premium range	\$0.19 to \$11.26	\$0.23 to \$6.08	\$0.23 to \$7.28	\$0.23 to \$7.28	\$0.23 to \$7.28
Prescriptions dispensed with a brand premium in the previous 12 months	26.0m	32.7m	30.9m	29.8m	27.5m
Prescriptions dispensed at the benchmark level in the previous 12 month period	5.4m	17.2m	20.8m	21.9m	23.3m
Percentage at the benchmark level	17%	34%	40%	42%	46%

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 Authority on a weighted average monthly treatment cost basis.

As at 30 June 1999 there were 86 items within the four groups under the TGP policy. These consisted of 126 brands at the benchmark price, 21 brands with a brand premium and 26 with a therapeutic premium. The TGP's ranged from \$0.78 to \$4.55.

Extra pricing procedure

A new pricing procedure came into effect from 1 May 1999 to allow variations to premiums and benchmark prices to occur with minimum delay.

The new procedure allows sponsors to vary premium prices or reduce benchmark prices without reference to the Authority. Applications for increases to the benchmark prices will continue to be considered by the Authority.

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 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 Australian Health Care Agreement 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 1999 there were thirty eight highly specialised drugs listed under Section 100.

Special patient contribution

There are currently two 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 Aged Care and the Department of Industry, Science and Resources, without the express permission of the Chairman and the company concerned.

Results of therapeutic group reviews 1998-99

In the 1998-99 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	1997-98	1998-99
Number of products reviewed	2,051	2,267
Number of products for which price applications were received	495 24.1%	654 28.8%
Number of products for which price increases were granted	158 7.7%	229 10.1%
Number of products for which price decreases were requested	28 1.4%	134 5.9%

The number of new items recommended for listing and new items actually listed for the financial year 1998-99 was:

Number of items recommended for listing by the Pharmaceutical Benefits Advisory Committee		76
	Section 100	12

(based on PBAC meetings held in 1998-99 financial year, includes different strengths)

Number of items listed		70
	Section 100	16

(based on new items listed in the PBS Schedules for 1998-99)

Estimated cost of price increases of existing items 1998-99

The general price increases granted to suppliers in 1998-99 are collectively estimated to add \$19.01 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	1997-98	1998-99
	\$ million	\$ million
Approved by Authority	0.20	0.78
Recommended by Authority and subsequently approved by the Minister	6.93	18.23
Total	7.13	19.01

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

Cost of Pharmaceutical Benefits Scheme, 1998-99

The total cost of pharmaceutical benefits for 1998-99 was \$3,396.98 million and comprised Commonwealth Government payments of \$2,795.64 million and patient contributions of \$601.34 million.

Category	Processed script numbers	Cost to Govt (excludes patient contributions)	Total cost
	\$ million	\$ million	\$ million
General	15.1	469.0	774.1
General safety net	4.1	106.6	119.8
Concessional	88.5	1,739.5	2,022.6
Concessional safety net	20.6	467.1	467.1
Miscellaneous Dr's Bag	0.6	13.4	13.4
Total	128.9	2,795.6	3,397.0

Note: For the general public, where a pharmaceutical benefit is priced below the general patient contribution (that is, \$20.30), the consumer pays the full amount including an additional dispensing fee of 85 cents provided that the total cost does not exceed \$20.30. The above figures do not include these amounts.

Chapter 3

Pharmaceutical Industry Development Program

The Pharmaceutical Industry Development Program aimed to encourage the development of an innovative and internationally competitive pharmaceutical industry in Australia. The Factor (f) Scheme was a major element of the program. The Scheme terminated on 30 June 1999. Under the Scheme, participating pharmaceutical manufacturers received notional and actual price increases for nominated products listed on the Pharmaceutical Benefits Scheme. In return, these companies committed to increases in manufacture, research, product and process development in Australia.

Factor (f) Scheme

Factor (f) is the sixth pricing factor. It requires the Authority to take into account the impact on industry development when recommending the price of pharmaceuticals. The Factor (f) Scheme was an important mechanism used by the Government to deliver on its commitment to industry development.

Phase I of the Scheme was introduced in 1988 and terminated in 1994-95. In light of the success of Phase I in encouraging additional pharmaceutical activity, Phase II was introduced on 1 July 1992. Final payments will be made to companies in late 1999, following receipt of audited data.

Participating companies

Ten companies participated in Phase II of the Scheme during 1998-99. The companies were:

- 3M Pharmaceuticals (Australia) Pty Ltd;
- AMRAD Corporation Limited;
- Astra Pharmaceuticals Pty Ltd (now AstraZeneca);
- CSL Limited;
- FH Faulding & Co Limited;
- Glaxo Wellcome Australia Limited;
- Merck Sharpe & Dohme (Australia) Pty Limited;
- Pfizer Pty Ltd;
- Pharmacia and Upjohn Pty Limited; and
- Rhône-Poulenc Rorer Australia Pty Ltd.

During 1998-99, the Commonwealth paid Factor (f) price increases totalling \$159 million. In return, the monitored performance of the Phase II companies for Australian Production Value Added (PVA) activity for the year totalled \$760 million compared with \$787 million for 1997-98. This represents a 1% decrease from the previous financial year's activity and an increase of \$627 million over the base year level (generally 1991-92). Expenditure on research and development in 1998-99 was \$109.4 million, compared with \$99 million in 1997-98. This represents an increase of 9% over the previous year's expenditure and an increase of \$97.4 over the base year level.

The cumulative total of Australian value added production from the commencement of Phase II of the Factor (f) Scheme to 30 June 1999 is \$3,586 million. The cumulative total expenditure on research and development is \$476.4 million. The amount paid by the Government for Phase II Factor (f) price increases to 30 June 1999 is \$710 million. The final amounts will be reported in the 1999-2000 Annual Report.

Events

Pharmaceutical Industry Investment Program

In April 1997, the Government announced the introduction of a new pharmaceutical industry assistance program—the Pharmaceutical Industry Investment Program (PIIP)—to run from July 1999 to June 2004. Like the Factor (f) Scheme, the PIIP will compensate the pharmaceutical industry, in part, for the impact on activity of the Government exercising its monopsony purchasing power under the Pharmaceutical Benefits Scheme. Companies participating in the PIIP will be entitled to partial compensation for the effects of price and volume constraints under the PBS by increasing either or both of their Production Value Added (PVA) and research and development (R&D) activities.

Applications to participate in the \$300 million PIIP closed on 15 August 1998. Twenty-two applications were assessed by an expert Panel appointed in August 1998 by the Ministers for Industry and Health. The Chairman of the Authority was a member of the Assessment Panel. Assessment of applications was based on merit and was consistent with the PIIP principles outlined in the Program Guidelines.

On 11 December 1998, the Minister for Industry, Science and Resources announced the names of 10 companies selected to participate in the PIIP. They were CSL Limited, F H Faulding & Co Ltd, AMRAD Corporation Ltd, Astra Pharmaceuticals Pty Ltd, Janssen-Cilag Pty Ltd, Eli Lilly Australia Pty Ltd, Pfizer Pty Ltd, Bristol-Myers Squibb Australia Pty Ltd, Pharmacia & Upjohn Pty Ltd, and Glaxo Wellcome Australia Pty Limited. Astra Pharmaceuticals has since withdrawn its application. Contracts with the participating companies have been signed.

On 24 May 1999, a report by the Australian National Audit Office on the PIIP selection process was tabled in Parliament. The report concluded that all applicants to the PIIP were treated ethically, equitably and fairly and appropriate steps were taken to maintain the confidentiality of commercial-in-confidence information. The report is available on the ANAO website at [www://www.anao.gov.au](http://www.anao.gov.au)

The Authority, supported by a Secretariat located within the Department of Industry, Science and Resources, will administer the PIIP.

Intellectual Property Laws Amendment Act 1998

The *Intellectual Property Laws Amendment Act 1998*, received Royal Assent on 15 July 1998 and came into force on 27 January 1999. The legislation recognises the long development times and regulatory requirements for new pharmaceuticals, which restrict the time under patent to exploit the invention and gain a return on investment. The Act's provisions bring Australia into line with the USA, EU and

Japan and ensure that pharmaceutical patents grant an 'effective life' similar to that available to inventions in other fields of technology. Standard and new 20 year patents for pharmaceutical inventions are eligible for an extension. 'Spring boarding' to meet pre-marketing regulatory approval requirements by generic producers is permitted from the date the extension of term for a patent is granted.

Pharmaceutical Industry Working Group

The Pharmaceutical Industry Working Group, continued under the auspices of the Minister for Health and Aged Care and the Minister for Industry, Science and Resources. Working party meetings were held during the year, with a formal meeting of the Working Group held on 30 June 1999. Both Ministers are committed to working with industry to develop a clear and positive policy framework that guarantees access to cost-effective medicines and maximises the development of the pharmaceutical industry in Australia into the next century.

Highlights for 1998-99 include:

- Glaxo Wellcome Australia received approval from the Therapeutic Goods Administration to market a major new influenza drug, Relenza™, in March 1999, with a launch in May 1999. The company will supply the Asia/Pacific region from 2000. The new production facility for the drug was opened in March 1999. Glaxo Wellcome have also established a Phase I clinical trial unit at the Prince of Wales Hospital and commenced clinical trials.
- Astra Pharmaceuticals opened its new \$60 million production facility at North Ryde. Covering 17,000 square metres, the facility is the largest, single, sterile, pharmaceutical plant in the southern hemisphere.
- Pfizer's new erectile dysfunction treatment, Viagra®, was introduced to the Australian market and contributed to the company's export earnings.
- AMRAD, together with the Ludwig Institute for Cancer Research, licensed the rights to their respectively owned VEGF-B (vascular endothelial growth factor B) gene patents and technology to Rhône-Poulenc Rorer Gencell, the gene therapy division of Rhône-Poulenc Rorer. The VEGF-B gene holds great promise as a new, more effective approach to treating patients with atherosclerotic heart disease, the leading cause of death in developed countries.
- Faulding's US-based Oral Pharmaceuticals business, Purepac, had seven Abbreviated New Drug Applications (ANDAs) approved by the US Food and Drug Administration (FDA) in the 1998 calendar year and was the first independent generic company to receive approval for five of those products. Soltec Research Pty Ltd, a wholly owned subsidiary of Faulding, announced that its US licensee, Connetics Corporation, received marketing clearance from the FDA for a pharmaceutical product incorporating a formulation developed by Soltec.

Chapter 4 – Tables and Figures

Table 1 Summary of ATC minor group reviews for 1998-99

ATC Code	Minor Group	No. of products reviewed	Script Volume	Govt Cost \$	Total Cost \$	Est.increase due to price inc.'s in a full year \$
C09	Agents acting on the renin-angiotensin system	78	10,818,873	244,488,089	326,935,446	47
V03	All other therapeutic products	11	22,725	1,297,636	1,361,260	731
N02	Analgesics	53	9,264,145	77,795,766	101,297,045	80,126
A02	Antacids, drugs for treatment of peptic ulcer and flatulence	96	8,489,989	340,318,092	396,847,224	71,244
N04	Anti- Parkinson drugs	37	534,451	19,397,377	21,950,082	9,473
R03	Anti-asthmatics	83	9,379,905	223,173,204	273,773,944	12,704,917
J01	Antibacterials for systemic use	256	11,462,183	128,028,772	165,509,147	108,808
A07	Antidiarrheals, intestinal antiinflammatory / antiinfectives	21	881,124	22,827,437	28,213,755	114,317
A04	Antiemetics & antinauseants	17	68,686	5,594,502	6,383,016	0
N03	Antiepileptics	48	1,290,837	58,966,446	68,026,281	354,834
M04	Antigout Preparations	12	775,164	5,888,006	7,874,655	441,753
C02	Antihypertensives	22	844,043	12,165,966	15,551,307	0
M01	Antiinflammatory and antirheumatic products	72	4,259,757	42,175,321	53,875,601	90,403
L01	Antineoplastic agents	94	212,162	37,738,719	39,484,548	1,887
A03	Antispasmodic and anticholinergic agents & propulsives	10	1,226,425	21,477,512	27,124,817	0
B01	Antithrombotic agents	40	1,482,371	17,460,744	21,466,669	13,760
J05	Antivirals for systemic use	51	241,573	48,360,859	51,616,733	0
C07	Beta blocking agents	39	3,636,455	34,672,355	45,746,571	0
B05	Blood substitutes and perfusion solutions	13	58,085	1,078,349	1,369,422	6,619
C08	Calcium channel blockers	54	7,366,808	143,426,867	185,722,551	422,665
C01	Cardiac therapy	49	3,236,469	54,932,030	64,431,637	136,603
H02	Corticosteroids for systemic use	31	1,418,471	9,167,453	13,201,812	4,798
D07	Corticosteroids, Dermatological Preparations	38	2,482,559	17,738,832	25,473,082	236,694
V04	Diagnostic Agents	21	426,129	18,714,090	20,676,792	124
C03	Diuretics	34	2,615,143	23,499,513	30,460,050	3,890
A10	Drugs used in Diabetes	59	3,025,216	99,211,563	109,543,303	0
L02	Endocrine therapy	29	328,135	68,031,043	70,396,479	31,347
V06	General nutrients	39	39,041	11,356,489	11,710,988	800,788
L03	Immunostimulants	38	27,653	30,744,549	31,051,627	0
L04	Immunosuppressive agents	11	81,385	5,911,645	6,647,392	0
A06	Laxatives	16	488,256	7,442,501	8,766,555	75,808
S01	Ophthalmologicals	104	4,708,129	51,993,742	66,083,567	341,618
S02	Otologicals	10	821,077	3,007,012	5,273,061	1,645
H01	Pituitary, Hypothalamic Hormones and Analogues	15	40,925	3,747,315	4,215,333	0
N06	Psychoanaleptics	59	7,416,154	177,555,372	229,429,230	0
N05	Psycholeptics	100	8,209,701	105,532,025	127,372,822	128,969
C10	Serum lipid reducing agents	33	7,782,201	363,354,083	422,499,059	0
G03	Sex hormones and modulators of the genital system	127	5,234,322	77,222,872	97,118,801	1,108,167
G04	Urologicals	11	383,808	11,984,170	13,720,228	69,548
	Others	336	7,840,633	168,165,591	198,778,940	1,651,409
	Total	2,267	128,921,168	2,795,643,906	3,396,980,832	19,012,992

**Table 2 Pharmaceutical Benefits Scheme
Highest Govt cost items—12 months to end June 1999**

Rank	Code	Drug	Form	Script Volume	Govt Cost \$	Total Cost \$	Ave Price \$
1	1327	Omeprazole	Capsule 20 mg	1,812,489	168,923,717	183,038,344	100.99
2	2012	Simvastatin	Tablet 20 mg	1,844,581	94,334,993	107,494,149	58.28
3	2011	Simvastatin	Tablet 10 mg	1,643,654	58,304,216	69,140,482	42.07
4	1978	Ranitidine Hydrochloride	Tablet 150 mg (base)	2,399,734	44,041,045	58,347,274	24.31
5	8214	Atorvastatin	Tablet 20 mg	760,841	44,009,520	50,954,230	66.97
6	8213	Atorvastatin	Tablet 10 mg	992,030	39,084,048	47,883,163	48.27
7	8187	Olanzapine	Tablet 10 mg	99,345	33,664,396	34,206,064	344.32
8	2242	Paroxetine	Tablet 20 mg (base)	997,453	33,154,502	42,573,682	42.68
9	2241	Lansoprazole	Capsule 30 mg	374,392	31,939,779	35,220,176	94.07
10	2592	Isotretinoin	Capsule 20 mg	161,510	28,019,642	30,404,891	188.25
11	8101	Interferon Beta - 1b	Injection set 1 vial powder dose 8,000,000 i.u.	21,573	27,017,036	27,256,086	1,263.44
12	1369	Enalapril Maleate	Tablet 20 mg	1,062,453	26,850,770	35,455,737	33.37
13	2834	Pravastatin	Tablet 20 mg	529,183	25,783,655	29,865,347	56.44
14	2236	Sertraline	Tablet 50 mg (base)	915,086	25,511,713	34,021,021	37.18
15	8215	Atorvastatin	Tablet 40 mg	284,844	25,323,332	27,882,535	97.89
16	8173	Simvastatin	Tablet 40 mg	341,062	25,312,892	27,873,715	81.73
17	2072	Budesonide	Oral inhal. 400mcg per dose (200 doses)	702,990	24,878,505	31,020,434	44.13
18	8238	Ipratropium Bromide	Nebuliser solution 500mcg in 1mL, 30	381,740	24,832,273	26,210,853	68.66
19	3051	Perindopril	Tablet 4 mg	1,013,453	22,644,123	31,130,323	30.72
20	2716	Fluticasone Propionate	Oral inhal. 250mcg per dose (120 doses)	454,378	21,891,827	25,359,522	55.81
21	1434	Fluoxetine Hydrochloride	Capsule 20 mg (base)	704,212	21,805,660	28,503,757	40.48
22	8003	Moclobemide	Tablet 300 mg	384,989	20,941,059	24,536,641	63.73
23	2502	Calcitriol	Capsule 0.25mcg	344,670	20,030,197	21,718,555	63.01
24	1149	Captopril	Tablet 50 mg	359,168	19,655,871	21,832,602	60.79
25	1746	Paracetamol	Tablet 500 mg	3,789,172	19,220,754	28,373,286	7.49
26	2237	Sertraline	Tablet 100 mg (base)	599,811	19,082,700	24,845,428	41.42
27	2367	Felodipine	Tablet 10 mg (extended release)	757,992	18,687,014	24,404,200	32.20
28	8093	Goserelin	Subcutaneous implant 10.8 mg (base)	16,149	18,621,225	18,723,322	1,159.41
29	8247	Irbesartan	Tablet 150 mg	857,064	18,034,141	25,273,351	29.49
30	1007	Aciclovir	Tablets 200 mg	92,987	17,299,078	18,625,096	200.30
31	1453	Gemfibrozil	Tablet 600 mg	458,706	17,295,441	20,626,729	44.97
32	2752	Amlodipine Besylate	Tablet 10 mg (base)	675,512	17,002,877	23,037,481	34.10
33	1215	Codeine with Paracetamol	Tablet 30 mg-500 mg	2,799,115	16,746,199	23,836,049	8.52
34	2751	Amlodipine Besylate	Tablet 5 mg (base)	1,166,021	16,682,194	25,312,921	21.71
35	1558	Isosorbide Mononitrate	Tablets 60 mg sustained release	1,025,772	16,481,335	18,874,658	18.40
36	2001	Salbutamol Sulfate	Nebuliser solution 5 mg in 2.5mL, 30	781,662	16,465,680	19,758,522	25.28
37	1081	Atenolol	Tablet 50 mg	2,118,943	15,175,336	20,990,096	9.91
38	1652	Beclomethasone Dipropionate	Oral inhal. 250mcg per dose (120 doses)	640,746	14,836,490	19,906,646	31.07
39	2430	Metformin Hydrochloride	Tablet 500 mg	1,169,099	14,642,422	17,792,671	15.22
40	2110	Tamoxifen	Tablet 20 mg (base)	178,944	14,596,279	15,955,382	89.16
41	3087	Salbutamol	Oral inhal. 100mcg per dose (200 doses)	1,861,161	14,561,899	19,400,009	10.42
42	8102	Alendronic Acid	Tablet equivalent to 10 mg alendronic acid	249,311	14,145,658	15,520,647	62.25
43	2458	Lisinopril	Tablet 20 mg	519,747	14,018,129	18,416,648	35.43
44	1946	Ramipril	Capsule 5.0 mg	602,402	13,914,359	18,791,055	31.19
45	1313	Diltiazem Hydrochloride	Capsule 240 mg (controlled delivery)	504,616	13,528,795	16,488,162	32.67
46	1368	Enalapril Maleate	Tablet 10 mg	755,582	13,525,664	19,418,298	25.70
47	8217	Famciclovir	Tablet 250 mg	23,331	13,270,706	13,612,609	583.46
48	1763	Insulin (Human)	Injection 100 units (30 units-70 units)	61,531	13,071,195	13,447,541	218.55
49	8243	Latanoprost	Eye drops 50mcg per mL (0.005%), 2.5 mL	375,914	12,506,284	14,652,349	38.98
50	3027	Salmeterol Xinafoate	Oral inhal. 25mcg (base) per dose (120 doses)	325,143	12,233,291	14,551,582	44.75

**Table 3 Pharmaceutical Benefits Scheme
Most prescribed items—12 Months to end June 1999**

Rank Code	Drug	Form	Script				
			Volume	Govt Cost \$	Total Cost \$	Ave Price \$	
1	1746	Paracetamol	Tablet 500 mg	3,789,172	19,220,754	28,373,286	7.49
2	1215	Codeine with Paracetamol	Tablet 30 mg-500 mg	2,799,115	16,746,199	23,836,049	8.52
3	1978	Ranitidine Hydrochloride	Tablet 150 mg (base)	2,399,734	44,041,045	58,347,274	24.31
4	1081	Atenolol	Tablet 50 mg	2,118,943	15,175,336	20,990,096	9.91
5	3087	Salbutamol	Oral inhal. 100mcg per dose (200 doses)	1,861,161	14,561,899	19,400,009	10.42
6	2012	Simvastatin	Tablet 20 mg	1,844,581	94,334,993	107,494,149	58.28
7	1327	Omeprazole	Capsule 20 mg	1,812,489	168,923,717	183,038,344	100.99
8	2011	Simvastatin	Tablet 10 mg	1,643,654	58,304,216	69,140,482	42.07
9	2430	Metformin Hydrochloride	Tablet 500 mg	1,169,099	14,642,422	17,792,671	15.22
10	2751	Amlodipine Besylate	Tablet 5 mg (base)	1,166,021	16,682,194	25,312,921	21.71
11	1369	Enalapril Meleate	Tablet 20 mg	1,062,453	26,850,770	35,455,737	33.37
12	1558	Isosorbide Mononitrate	Tablets 60mg sustained release	1,025,772	16,481,335	18,874,658	18.40
13	3051	Perindopril	Tablet 4 mg	1,013,453	22,644,123	31,130,323	30.72
14	2242	Paroxetine	Tablet 20 mg (base)	997,453	33,154,502	42,573,682	42.68
15	8213	Atorvastatin	Tablet 10 mg	992,030	39,084,048	47,883,163	48.27
16	2236	Sertraline	Tablet 50 mg (base)	915,086	25,511,713	34,021,021	37.18
17	8247	Irbesartan	Tablet 150 mg	857,064	18,034,141	25,273,351	29.49
18	2001	Salbutamol Sulfate	Nebuliser solution 5 mg in 2.5mL, 30	781,662	16,465,680	19,758,522	25.28
19	8214	Atorvastatin	Tablet 20 mg	760,841	44,009,520	50,954,230	66.97
20	2367	Felodipine	Tablet 10 mg (extended release)	757,992	18,687,014	24,404,200	32.20
21	1368	Enalapril Maleate	Tablet 10 mg	755,582	13,525,664	19,418,298	25.70
22	1434	Fluoxetine Hydrochloride	Capsule 20 mg (base)	704,212	21,805,660	31,023,757	40.48
23	2072	Budesonide	Oral inhal. 400mcg per dose (200 doses)	702,990	24,878,505	31,020,434	44.13
24	2752	Amlodipine Besylate	Tablet 10 mg (base)	675,512	17,002,877	23,037,481	34.10
25	1652	Beclomethasone Dipropionate	Oral inhal. 250mcg per dose (120 doses)	640,746	14,836,490	19,906,646	31.07
26	1946	Ramipril	Capsule 5 mg	602,402	13,914,359	18,791,055	31.19
27	2237	Sertraline	Tablet 100 mg (base)	599,811	19,082,700	24,845,428	41.42
28	2834	Pravastatin	Tablet 20 mg	529,183	25,783,655	29,865,347	56.44
29	2458	Lisinopril	Tablet 20 mg	519,747	14,018,129	18,416,648	35.43
30	1313	Diltiazem Hydrochloride	Capsule 240 mg controlled delivery	504,616	13,528,795	16,488,162	32.67
31	1453	Gemfibrozil	Tablet 600 mg	458,706	17,295,441	20,626,729	44.97
32	2716	Fluticasone Propionate	Oral inhal. 250mcg per dose (120 doses)	454,378	21,891,827	25,359,522	55.81
33	8003	Moclobemide	Tablet 300 mg	384,989	20,941,059	24,536,641	63.73
34	8238	Ipratropium Bromide	Nebuliser solution 500mcg in 1mL, 30	381,740	24,832,273	26,210,853	68.66
35	8243	Latanoprost	Eye drops 50mcg per mL (0.005%), 2.5 mL	375,914	12,506,284	14,652,349	38.98
36	2241	Lansoprazole	Capsule 30 mg	374,392	31,939,779	35,220,176	94.07
37	1149	Captopril	Tablet 50 mg	359,168	19,655,871	21,832,602	60.79
38	2502	Calcitriol	Capsule 0.25mcg	344,670	20,030,197	21,718,555	63.01
39	8173	Simvastatin	Tablet 40 mg	341,062	25,312,892	27,873,715	81.73
40	3027	Salmeterol Xinafoate	Oral inhal. 25mcg (base) per dose (120 doses)	325,143	12,233,291	14,551,582	44.75
41	8215	Atorvastatin	Tablet 40 mg	284,844	25,323,332	27,882,535	97.89
42	8102	Alendronic Acid	Tablet equivalent to 10 mg alendronic acid	249,311	14,145,658	15,520,647	62.25
43	2110	Tamoxifen	Tablet 20 mg (base)	178,944	14,596,279	15,955,382	89.16
44	2592	Isotretinoin	Capsule 20 mg	161,510	28,019,642	30,404,891	188.25
45	8187	Olanzapine	Tablet 10 mg	99,345	33,664,396	34,206,064	344.32
46	1007	Aciclovir	Tablets 200 mg	92,987	17,299,078	18,625,096	200.30
47	1763	Insulin (Human)	Injection 100 units (30 units-70 units)	61,531	13,071,195	13,447,541	218.55
48	8217	Famciclovir	Tablet 250 mg	23,331	13,270,706	13,612,609	583.46
49	8101	Interferon Beta - 1b	Injection set 1 vial powder dose 8,000,000 i.u.	21,573	27,017,036	27,256,086	1,263.44
50	8093	Goserelein	Subcutaneous implant 10.8 mg (base)	16,149	18,621,225	18,723,322	1,159.41

**Table 4 Top 20 suppliers by total cost 1998-99
(from processed PBS prescriptions)**

Rank	Supplier(s)	Script Volume	Govt Cost \$	Total Cost \$	Sales to Ex-supplier
1	Astra	7,495,272	285,741,266	326,889,047	240,839,645
2	Merck Sharp & Dohme	7,616,933	212,157,938	258,221,979	184,225,492
3	GlaxoWellcome	9,771,180	197,753,129	248,620,412	168,720,129
4	Alphapharm	12,001,539	147,601,307	185,781,995	109,387,077
5	Parke Davis	4,095,173	141,637,320	169,674,061	124,282,645
6	Bristol-Myers Squibb	4,276,078	122,959,968	152,159,288	109,309,998
7	Pfizer	4,778,111	96,464,256	130,044,086	89,433,062
8	Roche	3,700,853	111,898,519	128,994,981	92,399,956
9	Amrad	2,878,418	97,227,956	116,752,497	85,303,769
10	SmithKline Beecham	3,528,631	87,059,569	105,605,309	73,874,496
11	Pharmacia & Upjohn	2,984,415	86,807,161	101,120,100	72,137,241
12	Zeneca	2,861,271	83,347,030	98,020,215	70,038,244
13	WyethAustralia	4,780,129	79,637,006	97,242,781	62,588,472
14	Eli Lilly	2,439,863	71,392,191	83,280,977	59,475,250
15	Novartis	3,734,350	63,729,045	77,822,302	50,412,455
16	Hoechst Marion Roussel	4,154,559	57,411,373	76,289,464	47,666,191
17	Sanofi-Synthelabo	6,881,833	48,458,179	68,447,146	31,565,447
18	Rhone-Poulenc Rorer	3,600,328	49,913,463	64,179,138	39,725,766
19	Novo Nordisk	727,430	58,167,027	61,819,473	47,996,531
20	Schering	1,216,273	52,19,045	58,678,420	43,690,742
	Others	35,398,527	644,160,708	787,337,161	518,487,999
	Total	128,921,168	2,795,643,906	3,396,980,832	2,321,560,606

Note includes branded and unbranded scripts, agents, distributors, etc. contained into other

**Table 5 Top 20 suppliers by market share for 1998-99
(from processed PBS prescriptions)**

Rank	Suppliers	Script Volume	% of Total	Govt Cost \$	Total Cost \$	Sales to Ex-supplier
1	Alphapharm	12,001,539	9.31%	147,601,307	185,781,995	109,387,077
2	Glaxo Wellcome	9,771,180	7.58%	197,753,129	248,620,412	168,720,129
3	Merck Sharp & Dohme	7,616,933	5.91%	212,157,938	258,221,979	184,225,492
4	Astra	7,495,272	5.81%	285,741,266	326,889,047	240,839,645
5	Sanofi-Synthelabo	6,881,833	5.34%	48,458,179	68,447,146	31,565,447
6	Wyeth Australia	4,780,129	3.71%	79,637,006	97,242,781	62,588,472
7	Pfizer	4,778,113	3.71%	96,464,256	130,044,086	89,433,062
8	Bristol - Myers Squibb	4,276,078	3.32%	122,959,968	152,159,288	109,309,998
9	Hoechst Marion Roussel	4,154,559	3.22%	57,411,373	76,289,464	47,666,191
10	Parke Davis	4,095,173	3.18%	141,637,320	169,674,061	124,282,645
11	Sigma	3,951,772	3.07%	38,578,268	51,389,543	28,013,607
12	Novartis	3,734,350	2.90%	63,729,045	77,822,302	50,412,455
13	Roche	3,700,853	2.87%	111,898,519	128,994,981	92,399,956
14	Rhone-Poulenc Rorer	3,600,328	2.79%	49,913,463	64,179,138	39,725,766
15	SmithKline Beecham	3,528,631	2.74%	87,059,569	105,605,309	73,874,496
16	Pharmacia & Upjohn	2,984,415	2.31%	86,807,611	101,120,100	72,137,241
17	Amrad	2,878,418	2.23%	97,227,956	116,752,497	85,303,769
18	Zeneca	2,861,271	2.22%	83,347,030	98,020,215	70,038,244
19	Eli Lilly	2,439,863	1.89%	71,392,191	83,280,977	59,475,250
20	Servier	2,295,334	1.78%	40,925,366	54,856,268	36,731,879
	Others	31,095,124	24.12%	674,943,145	801,589,243	545,429,786
	Total	128,921,168	100.00%	2,795,643,905	3,396,980,832	2,321,560,606

Note: includes branded and unbranded scripts and Doctor's bag scripts written for EP items in 'Other' total.

Unbranded scripts totalled 10.5 million (cost \$242.6 million) or 8.17 per cent of total processed scripts.

Table 6 (a) Significant Drug Groups - 12 months to end June, sorted by highest Government end 1998 - 99

		12 months year 1997-98				Financial year 1998-99			
ATC Code	Major Group	Script Volume	Total Cost \$	Avg Price \$	Script Volume	Total Cost \$	Avg Price \$	Total Cost \$	Avg Price \$
C10	Serotonin-releasing Agents	6,144,060	275,849,121	44.90	7,383,251	565,354,081	76.45	422,470,049	57.23
A02	Anesthetics, drugs for treatment of people with and without	8,062,793	322,433,127	40.00	8,489,949	401,719,002	47.33	196,807,324	23.07
U09	Agents acting on Renin-Angiotensin System	5,709,043	245,626,560	42.86	10,818,877	218,988,028	20.24	326,015,486	30.12
R05	Anti-Asthmatics	9,420,685	214,902,739	22.81	9,179,925	223,173,204	24.32	235,778,944	25.80
L10	Psychotropics	6,264,716	150,349,287	24.00	7,415,114	173,351,371	23.37	229,429,110	30.68
S06	Calcium Channel Blockers	7,499,707	151,094,202	20.15	7,166,808	144,926,367	20.22	183,272,551	25.59
J01	Antibacterials, systemic use	14,094,024	134,018,459	9.51	11,462,187	128,028,772	11.17	165,578,147	14.44
N05	Psychotropics	7,974,141	70,177,025	8.80	8,209,751	155,232,225	18.91	127,372,821	15.51
A10	Antidiabetic Therapy	2,694,226	69,893,223	25.94	3,225,216	99,211,501	30.74	169,543,101	52.58
N03	Anesthetics	9,229,282	72,289,428	7.84	9,264,145	19,795,766	2.14	161,299,049	18.17
B04	Antihypertensives and modulators of the renal system	4,993,708	72,274,163	14.47	5,316,372	77,271,872	14.54	87,111,801	16.38
A02	Anesthetics	3,153,221	29,215,601	9.27	3,728,173	68,021,593	18.25	70,398,479	18.70
M07	Antiepileptics	1,214,374	22,331,741	18.39	1,240,877	29,864,346	23.99	48,026,281	38.70
O01	Contraceptives	3,334,812	29,846,311	8.95	3,236,480	54,932,026	16.98	66,411,637	19.91
S01	Opioid Analgesics	4,444,605	41,790,702	9.38	4,708,129	51,983,141	10.99	66,086,267	14.04
A15	Antidiabetic for systemic use	232,246	27,167,810	117.33	241,573	48,300,458	200.00	51,616,727	213.67
M01	Anti-inflammatory and antirheumatic products	4,245,338	42,331,847	10.00	4,439,792	42,173,171	9.49	55,871,801	12.64

		Percentage Change							
ATC Code	Major Group	Script Volume	Total Cost \$	Avg Price \$	Script Volume	Total Cost \$	Avg Price \$	Total Cost \$	Avg Price \$
C10	Serotonin-releasing Agents	1,938,191	81,694,933	42.18	220,775	32,688	148.10	311,382	142.80
A02	Anesthetics, drugs for treatment of people with and without	427,205	17,889,265	41.86	53,686	545,986	101.70	587,672	115.50
U09	Agents acting on Renin-Angiotensin System	1,199,828	1,881,529	156.88	14,118	161,299,049	1141.00	209,987	1420.00
R05	Anti-Asthmatics	26,734	8,390,444	313.60	22,642	23,508	1038.00	1,690,646	7468.00
C10	Psychotropics	811,478	21,208,295	26.14	1,077,925	29,745,982	27.61	33,008	124.00
S06	Calcium Channel Blockers	132,899	1,667,227	12.55	1,277	1,277	1000.00	5,528	4348.00
J01	Antibacterials for systemic use	628,844	199,647	31.76	5,571	2,094,718	376.00	41,191	7384.00
N05	Psychotropics	233,158	35,019,940	150.10	4,005	495,795	123.79	19,724	4937.00
A10	Antidiabetic Therapy	331,695	10,116,310	30.50	1,571,579	11,005	7000.00	11,005	438.00
A10	Antidiabetic Therapy	91,169	3,701,728	40.60	6,698	78,228	1168.00	85,008	531.00
B04	Antihypertensives and modulators of the renal system	246,254	4,148,259	16.85	4,768,968	6,118	128.00	21,678	31.00
B04	Antihypertensives	12,314	8,791,242	714.00	8,866,921	19,440	220.00	144,128	654.00
S01	Opioid Analgesics	56,201	6,631,703	117.99	9,700,257	1,241	12.00	114,298	650.00
C01	Cardiac Therapy	89,441	1,906,445	21.32	2,667	6,668	250.00	7,186	432.00
S01	Opioid Analgesics	203,464	10,627,040	52.24	1,391,014	3,396	2.00	23,688	171.00
B05	Antidiabetic for systemic use	29,427	11,792,049	399.00	25,117	50,828	2024.00	29,878	1190.00
M01	Anti-inflammatory and antirheumatic products	14,401	1,561,226	108.33	4,107	4,107	23.00	2,395	578.00

Table 4(b). Significant Drug Groups - 12 months to end June, sorted by highest script volume 1998 - 99

ATC Code / Major Groups		Financial year 1998 - 99						
ATC Code	Major Groups	Script Volume	Cross User \$	Total Cost \$	Ave Price \$	Script Volume	Total Cost \$	Ave Price \$
B01	Antibacterials for systemic use	12,041,657	228,528,939	167,165,861	13.87	11,462,185	126,028,792	10,912,147
C09	Agents acting on Renin-Angiotensin System	9,795,247	292,666,360	317,611,481	32.52	10,815,875	234,483,089	21,635,946
B03	Anti-fungal	9,000,649	214,562,339	364,526,303	38.12	9,379,925	231,173,204	24,531,944
S01	Analgesics	9,201,795	72,289,674	95,565,372	10.38	9,166,144	97,745,166	10,652,045
N02	Anticancer drugs (excl. treatment of leukaemia and lymphoma)	4,162,755	124,428,223	674,583,906	46.38	4,489,939	340,318,072	75,847,224
N03	Psychotropics	7,974,343	70,512,083	91,164,759	11.43	8,209,251	105,532,628	12,732,812
C10	Sexual health/contraceptives	6,344,060	273,879,134	322,142,936	50.78	7,782,251	363,354,083	46,570,199
S08	Psychostimulants	4,584,716	135,349,203	199,685,328	30.13	7,415,154	171,353,177	23,129,770
C08	Calcium Channel Blockers	1,499,237	131,084,102	196,612,436	26.72	1,166,808	143,026,467	18,722,251
G02	Sex hormones and modulation of the genital system	4,901,708	78,276,161	92,549,393	14.49	5,234,322	71,222,472	9,718,862
S02	Psychic/psychotropics	4,444,663	41,370,702	53,692,353	12.07	4,708,129	51,984,742	6,503,367
S01	Antipsychotics and Anticholinergics	4,245,576	42,331,447	54,020,353	12.72	4,259,237	42,175,121	5,181,667
C09	Heart Resin/Resin Agents	1,483,436	28,749,113	39,236,453	11.16	1,636,455	14,673,135	45,766,371
C01	Cardiac Therapy	1,784,992	36,481,511	69,351,878	26.72	1,276,469	34,932,080	64,401,637
A1C	Antidiabetic Therapy	2,074,176	38,693,251	57,971,724	26.36	2,027,216	59,211,592	109,543,363
U28	Diuretics	2,591,154	22,292,236	29,673,274	11.45	2,612,143	23,490,511	30,660,050
S07	Cardiovascular / Dermatological preparations	2,448,722	16,565,119	24,138,821	9.77	2,482,259	17,794,632	22,475,082
Percentage Change:								
ATC Code / Major Groups	Script Volume	Cross User \$	Total Cost \$	Ave Price \$	Script Volume	Total Cost \$	Ave Price \$	
B01	Antibacterials (in systemic use)	-482,687	-2,094,714	-5.47	-514%	-10%	-129%	-410%
C09	Agents acting on Renin-Angiotensin System	1,816,329	9,304,245	2.36	1741%	7%	293%	763%
B03	Anti-fungal	6,594,444	6,170,843	3.00	-27%	400%	156%	378%
S01	Analgesics	3,106,178	3,731,670	-2.75	66%	762%	694%	511%
N02	Anticancer drugs (excl. treatment of leukaemia and lymphoma)	27,885,167	21,287,334	-2.16	570%	55%	56%	1%
N03	Psychotropics	35,019,940	36,208,468	4.28	293%	491%	197%	1%
C10	Sex hormones and modulation of the genital system	39,494,451	150,346,124	3.51	2167%	1240%	311%	62%
N06	Calcium Channel Blockers	21,216,277	39,741,002	2.16	1267%	27%	189%	20%
C08	Psychostimulants	7,667,235	10,969,989	1.06	177%	-507%	-453%	-364%
G02	Sex hormones and modulation of the genital system	4,448,769	4,764,908	5.06	482%	61%	41%	1%
S08	Psychostimulants	10,622,646	22,397,614	1.36	593%	330%	210%	101%
S02	Psychic/psychotropics	-146,526	-184,820	-2.70	-14%	17%	-27%	-27%
C07	Beta Blockers	5,923,242	6,110,438	1.22	439%	265%	165%	116%
C01	Cardiac Therapy	-9,903,482	-5,202,341	-3.10	-366%	-46%	-76%	-46%
A11	Antidiabetic Therapy	10,516,110	11,577,279	-6.15	122%	110%	181%	43%
C02	Diuretics	702,381	984,626	0.20	89%	310%	304%	174%
S07	Cardiovascular / Dermatological preparations	1,172,111	1,344,261	2.49	56%	76%	57%	46%

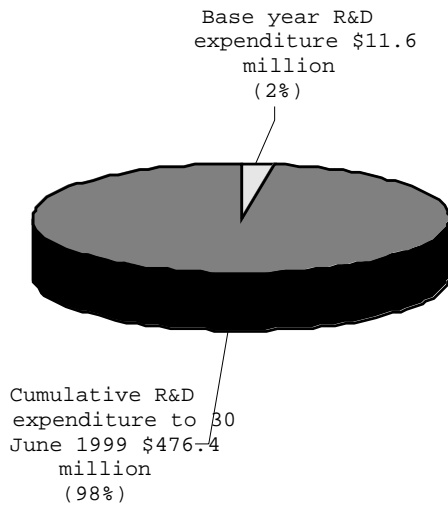
Table 7 (R) PBS Drugs comparisons (with Dr. Bag), sorted by biggest change to Government cost 1998 - 99

Rank	Drug	1997 - 98			1998 - 99			Volume	From Cost \$	Total Cost \$	Avg Price \$	Variance	% Change
		Value	Cost/Cost \$	Total Cost \$	Value	Cost/Cost \$	Total Cost \$						
1	Atenolol	241,045	12,023,343	14,429,512	59,708	150,416,301	1,267,190,238	62.119	96,308,354	911.27%			
2	Clonidine	71,293	18,031,439	18,498,545	239,940	48,481,337	46,989,668	239.15	30,840,974	7100%			
3	Chlorzoxazone	1,597,536	115,355,065	138,132,598	98,588	175,506,849	1,033,077,663	140.30	30,331,484	2400%			
4	Ethinodiol	37,560	305,646	321,171	29,638	29,359,597	40,227,963	30.35	38,973,353	74000%			
5	Fludione	380,339	18,004,390	21,092,460	59,940	30,756,832	36,420,541	51.10	12,352,248	7600%			
6	Lacosamide	7,261	334,621	782,270	38,431	12,306,284	14,652,349	38.98	12,271,461	132500%			
7	Salicylic Acid	49,117	8,395,674	8,865,302	100,711	15,344,917	21,196,129	209.75	11,047,543	54000%			
8	Lacosamide	373,207	27,783,437	30,581,136	91,600	15,305,667	19,179,078	99.97	8,332,746	5260%			
9	Omipoxol and Ciprofloxacin and Amoxicillin	C	0	C	34,805	4,614,119	8,881,436	178.09	8,019,337	53%			
10	Claisipran	31,393	341,913	770,234	34,000	3,444,357	11,516,041	18.41	7,902,641	145000%			
11	Quinapril	453,033	9,925,409	13,447,914	20,23	13,231,359	23,230,129	18.21	7,730,944	73700%			
12	Quinapril	132,698	9,304,343	10,487,996	93,256	17,5424	15,591,995	17,068,323	98.59	8,062,436	6010%		
13	Acetaminophen	16,517	21,093,878	21,394,666	226,988	27,217,000	27,256,098	1,263.44	5,821,159	2740%			
14	Acetaminophen	1,294,105	33,724,272	30,451,103	41,771	44,914,435	38,866,348	38.86	5,612,140	1430%			
15	Cisplatin	977	74,467	81,143	87,46	4,057,674	5,737,379	19.47	4,798,207	6403%			
16	Insulin (Human)	356,023	54,990,237	57,958,676	162,311	59,719,652	62,906,146	158.10	4,729,453	1000%			
17	Propranolol	892,196	41,851,666	49,035,911	54,396	66,543,189	69,994,385	76.55	4,691,371	1370%			
18	Traudolapril	530,303	16,489,376	15,184,623	24,840	14,533,825	21,358,116	46.23	4,294,426	9200%			
19	Scopolamine	674,297	7,743,350	23,700,119	33,116	23,899	23,800,071	28,184,704	38.88	4,062,641	1660%		
20	Alendronate Acid	173,179	12,905,919	13,911,408	86,533	15,779,142	16,247,323	58.23	3,873,383	3000%			
21	Parecoxib	360,001	26,101,000	27,981,982	49,164	31,139,922	42,377,982	42.69	3,772,832	1384%			
22	Concortin	49,144	26,674,764	27,046,992	543,72	49,431	10,709,471	621.94	3,753,307	1407%			
23	Repaglinide	104,344	15,436,865	16,031,174	151,12	19,217,432	19,681,992	143.33	3,482,457	2370%			
24	Salmeterol	274,592	16,920,262	16,936,910	66,371	14,201,720	17,016,597	45.34	5,371,311	3500%			
25	Etiopiridine	42,257	7,728,496	2,042,565	48,23	4,992,828	5,986,149	45.54	5,294,241	1000%			
26	Calcitriol	290,220	16,899,155	18,083,311	62,99	20,030,197	21,218,555	63.61	5,201,040	1910%			
27	Vincristine	232,091	14,582,259	16,323,442	72,11	16,961,739	20,242,163	27.81	2,878,204	2644%			
28	Rituximab	0	0	0	1,374	3,757,174	2,775,181	2,014.00	2,959,174	52.10			
29	Prednisone	2,651	3,667,708	3,706,354	21,957.31	8,392,248	8,477,209	2,077.54	2,077,541	470%			
30	Doxycycline	1,947	1,887,661	3,912,345	2008.37	6,481,038	6,521,738	1,899.58	2,593,357	1671%			
31	Lacosamide	106,331	11,203,924	11,879,889	118.46	13,697,179	14,512,319	120.46	2,488,445	2320%			
32	Ibuprofen	151,303	26,003,896	29,279,635	184.84	38,409,465	30,860,143	185.19	2,466,605	926%			
33	Methotrexate Hydrochloride	1,172,537	11,894,532	16,992,166	14,111	15,329,873	16,331,472	19,920,100	15,253	2,399,120	1716%		
34	Pentoxifylline	1,271,327	27,511,278	30,026,118	29,941	32,707,761	41,694,462	38.21	2,194,482	7986%			
35	Phenacetin	44,745	1,111,967	1,340,724	46.91	1,129,404	4,413,712	42.27	1,997,200	1,694%			

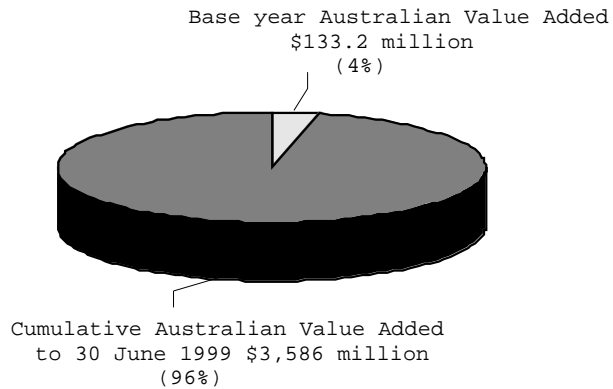
Table 7 (B) PBS Drugs 12 months comparison (with Drs Bug), sorted by variation in volume (script usage) 1998 - 99

Drug	1997-98				1998-99				Variation		
	Script Volume	Cost Cont \$	Total Cost \$	Ave Price \$	Script Volume	Cost Cont \$	Total Cost \$	Ave Price \$	Cost Cont \$	Total Cost \$	% Change
1 Atorvastatin	34,505	17,028,141	14,409,172	59.79	2,017,715	1,084,416,801	126,719,928	62.19	1,986,679	149,679	149.9%
2 Inositol	17,390	365,646	321,171	29.64	1,308,587	29,139,397	40,219,561	30.71	1,291,627	370,086	370.08%
3 Quasipil	453,248	9,220,409	13,647,914	30.13	823,337	11,211,359	35,720,179	38.21	3,701,539	3,716	3.71%
4 Lateralpad	1,301	21,4921	302,717	38.94	119,914	12,926,291	24,622,749	38.98	358,651	1,949,994	1,949.99%
5 Paricalcitol	189,319	10,064,590	21,912,460	51.94	711,292	30,736,832	36,410,543	41.19	511,951	1,794	1.79%
6 Sertraline	1,209,107	38,472,372	50,451,172	41.73	2,154,897	44,594,414	48,306,448	38.86	393,797	786	78.6%
7 Bimatoprost	3,226,759	78,133,900	99,382,934	30.76	1,527,266	64,153,590	86,271,196	34.46	300,547	318	31.8%
8 Omeprazole	1,591,535	143,551,665	158,222,990	98.94	1,891,165	171,456,349	190,637,642	100.80	239,627	26	2.6%
9 Tirofiban	3,910	10,692,176	15,164,011	38.60	813,971	11,935,405	21,368,116	26.24	284,602	367	36.7%
10 Cefepime	2,292	341,913	770,274	33.60	299,825	846,557	1,139,641	38.41	278,666	513	51.3%
11 Povidone	1,271,227	27,513,278	34,226,718	29.91	1,473,030	29,727,261	41,604,460	28.21	279,787	748	74.8%
12 Metformin Hydrochloride	1,322,557	13,082,352	16,997,260	12.13	1,307,674	16,381,472	29,920,808	15.21	185,616	1374	13.74%
13 Perindolol	862,401	29,381,680	37,248,089	43.14	947,475	31,193,302	42,573,692	42.68	137,626	475	47.5%
14 Nifedipine	158,409	3,989,898	7,638,142	39.41	915,421	7,220,645	9,838,439	34.86	17,911	234	23.4%
15 Ranitidine	353,709	18,076,475	24,722,800	24.90	980,232	19,890,117	27,280,507	27.81	124,721	69	6.9%
16 Diazepam	7,297	18,033,459	14,458,345	326.90	193,979	48,881,387	49,994,698	259.17	121,634	678	67.8%
17 Vanilansin	232,294	14,682,109	16,223,442	75.18	350,149	16,981,074	20,247,303	37.81	17,592	133	13.3%
18 Warfarin	1,609,465	5,020,281	7,520,859	7.45	1,016,879	5,693,012	8,398,619	7.48	17,414	234	23.4%
19 Mometasone and budesonide	307,063	17,991,009	4,801,075	15.98	418,087	3,277,453	6,583,159	15.72	111,631	297	29.7%
20 Atenolol	2517,464	14,106,846	19,636,400	9.87	2,118,945	13,175,326	20,090,626	9.91	156,476	146	14.6%
21 Glimepiride	335,890	6,810,743	4,196,278	13.41	626,742	8,189,257	9,828,640	15.44	164,902	154	15.4%
22 Salicylic acid	276,792	10,920,202	12,936,899	46.77	376,827	14,291,220	17,101,577	45.14	190,213	924	92.4%
23 Morphine	624,041	21,743,190	23,780,774	36.10	723,989	23,866,051	28,146,194	38.86	99,888	464	46.4%
24 Aspirin	671,079	2,613,581	4,283,379	5.32	777,033	3,700,077	4,647,078	5.96	38,854	379	37.9%
25 Furosemide	191,201	27,162,927	30,098,156	91.00	418,698	35,195,067	39,177,128	93.57	95,483	15	1.5%
26 Alendronate	77,175	12,949,319	11,911,488	89.33	267,429	16,779,542	18,247,223	68.21	34,304	774	77.4%
27 Mometasol	42,237	1,728,266	2,040,064	48.28	130,821	4,992,328	5,936,349	45.31	84,164	3124	312.4%
28 Omeprazole and Ursolic acid and ursolic acid	9	0	0	N/E	81,881	8,024,233	8,851,476	108.09	21,891	N/E	N/E
29 Teniposon	2,406,061	9,337,956	13,108,229	5.36	1,483,873	8,045,628	8,816,127	6.26	79,312	834	83.4%
30 Arsenic trioxide and Cytarabine and	2,986,076	11,657,677	16,087,685	12.10	1,175,054	17,183,946	26,620,920	13.82	78,979	38	3.8%
31 Mometasone	178,903	3,774,190	5,176,699	11.77	447,871	4,564,251	6,244,928	13.94	10,828	189	18.9%
32 Pyridoxine	891,186	41,851,466	49,215,911	54.96	962,119	46,345,189	53,961,385	46.11	69,914	278	27.8%
33 Cholestanol	1,446,980	6,234,232	5,710,434	6.71	1,513,523	6,189,613	10,179,348	6.73	66,313	1094	109.4%
34 Propofol	212,698	9,504,563	10,487,996	91.06	173,414	15,391,997	17,089,727	98.59	60,728	64	6.4%
35 Cocaine with ruscogenol	2,176,298	13,818,624	24,622,781	8.27	2,876,366	14,896,462	24,091,102	8.45	60,288	18	1.8%

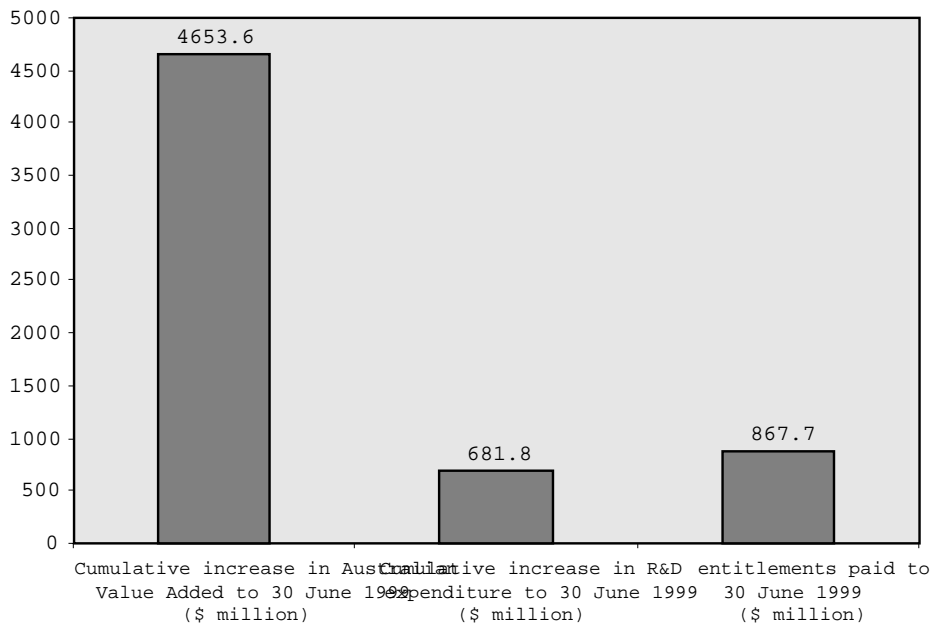
Factor (f) - Research and development expenditure in Phase
30 June 1999



Factor (f) - Australian Value Added activity in Phase II
30 June 1999



Factor (f) - Increase in activity versus entitlements
 (Phase I and Phase II)



Appendix: Factor (f) Pricing Guidelines issued June 1992

Role of the Authority

The Authority will:

- consider proposals received from companies for price increases under factor (f);
- recommend approval or otherwise to the Minister for Industry, Science and Technology and the Minister for Human Services and where appropriate, the value of any price increases to be offered to companies;
- monitor companies' performance against their proposals to ensure price increases are commensurate with the level of activity companies achieve; and
- discuss with companies additional activity or lower price levels in the event a company's performance is below the level forecast in its proposal.

Principles

The Factor (f) Pricing Guidelines under which higher prices will be paid are based on four fundamental principles:

- prices for pharmaceuticals listed on the Pharmaceutical Benefits Scheme should not be an impediment to the significant development of the industry;
- higher prices should only be recommended if they are likely to contribute to the development of significant internationally competitive activity in Australia;
- Pharmaceutical Benefits Scheme prices should not exceed the average prices of pharmaceutical products in the European Community; and
- a net benefit to the economy should result from any price increases granted on the basis of Australian activity.

Timeframe

Activity undertaken in the period from 1 July 1992 to 30 June 1999 will be eligible for price increases from and including the company financial year in which their proposal is lodged with the Authority.

Definitions

Pharmaceuticals—are human use pharmaceuticals of the type currently available under the Pharmaceutical Benefits Scheme and include biologically active products and systems.

Production—is the manufacture for export or domestic sale of pharmaceutical products, raw materials or material inputs into finished pharmaceutical products. Production is valued at ex-factory prices.

Exports—includes sales from Australia to other countries of products, active ingredients, raw materials for use in pharmaceutical products, and income derived from royalties and similar payments from other countries.

The Authority will consider the inclusion of exports of pharmaceutical related services on a case by case basis. Exports of pharmaceutical products are valued at free on board prices.

Imports—is the landed cost of imported pharmaceutical products, active ingredients, and components used in the production or packaging of pharmaceuticals. Landed cost includes expenditure on royalties and similar payments.

Value added—is the difference between the ex-factory selling price and the landed cost of imported ingredients, materials and royalties and similar payments. Value added can include income from royalties and similar payments.

Turnover—is total sales of pharmaceuticals at ex-factory prices.

Research and development (R&D)—is generally as defined by the Industry Research and Development Board for the purpose of applying the Industry Research and Development tax concession.

To be approved for price increases, R&D will need to have the potential for use in the development of pharmaceutical products and processes, or in the application of pharmaceuticals.

New entrant—is a company which first participates in the Factor (f) Scheme after 1 July 1992.

Continuing participant—is a company which participated in the Factor (f) Scheme before 1 July 1992.

Base year—is the year which is used as the base over which increases in activity are measured.

For new entrants in the scheme, the base year will generally be the company's operating year prior to approval of a factor (f) proposal. Continuing participants in the scheme will generally maintain their existing base year.

Participation requirements

To receive price increases under factor (f), companies must lodge proposals with the Pharmaceutical Benefits Pricing Authority detailing the activity they propose to undertake under the scheme.

Proposals for price increases should be detailed plans for new and expanded R&D and production. Companies will need to demonstrate their proposals are integrated with the long term strategic direction of the company as a whole. Companies must

also provide forecast data for activity over the period of the proposal and audited data for activity in the base year.

Once the Authority has reviewed a proposal it will make a recommendation on approval to the Minister for Industry, Science and Technology and the Minister for Human Services and Health. If the Government agrees with the Authority's assessment that a company has demonstrated it can meet the requirements for entry into the scheme, the company will be eligible for price increases under factor (f).

New entrants to the scheme will be eligible for factor (f) price increases if they are able to demonstrate their proposed activity is internationally competitive and will provide significant net benefits to Australia. New entrants will either meet specific eligibility criteria or demonstrate their proposal should be eligible on qualitative grounds.

Continuing participants in the scheme will be eligible for additional price increases where they can demonstrate their proposed new activity is internationally competitive and will provide significant net benefits to Australia. The Authority will discuss appropriate performance targets and price increases with these companies and will make a recommendation to the Minister for Industry, Science and Technology and the Minister for Human Services and Health.

Eligibility criteria

Proposals from companies entering the scheme after 1 July 1992

All new entrants will be required to demonstrate their proposed activity is internationally competitive and will provide significant net benefits to Australia. Companies will generally enter the scheme by demonstrating their commitment to meet two eligibility criteria within five years of approval.

The Authority recognises there may be circumstances in which a company, while making a significant contribution to internationally competitive activity in Australia, is unable to meet these eligibility criteria. In such circumstances, the Authority may recommend price increases on qualitative grounds.

The new entrant must undertake to meet one of the following two eligibility criteria within three years of entry into the scheme, and the other within five years of entry into the scheme.

- **Production**

- Increase the value added in Australia on pharmaceutical production by 50 per cent over a three year period.

- **Research and development**

- Achieve a level of R&D spending equal to 3 per cent of turnover and maintain R&D spending at 3 per cent of turnover for the remainder of the scheme.

However, a company able to demonstrate it can meet the eligibility will not automatically qualify for factor (f) price increases. Approval of price increases is dependent on the assessment of the international competitiveness of the proposed activity and of the net benefits which will accrue to Australia from the activity.

Where a company is unable to meet the eligibility criteria above, the Authority may recommend price increases if the company is able to demonstrate it is substantially increasing its activity in Australia and the activity is internationally competitive and is likely to lead to significant net benefits for Australia.

The purpose of this provision is not to bypass the stringency or intent of the eligibility criteria, but to provide some flexibility in cases where a company's development strategy is no less ambitious.

In deciding whether to recommend approval of a proposal on qualitative grounds, the Authority will consider the activity proposed by the company including:

- new active ingredient production;
- new investment in production plant, facilities or equipment;
- expenditure on new research and development projects;
- new production for export and domestic sale;
- commitment to best manufacturing practice through measures such as benchmarking, quality program and workplace reform;
- establishment of Australia as a centre for operations in the Asia/Pacific region; and
- other internationally competitive activity.

Once a new entrant has demonstrated it can meet its proposed eligibility criteria, or has been approved on qualitative grounds, the Authority will discuss with the company performance targets for the:

- remainder of the proposal where a company meets the eligibility criteria; or
- entire proposal where a company has been approved on qualitative grounds.

The targets will initially be determined at the time of approval of a proposal. Performance targets will generally be growth rates for increases in research and development and value added production.

New proposals from participants in the scheme prior 1 July 1992

New or revised proposals for price increases under the factor (f) scheme from companies participating in the scheme prior to 1 July 1992, must include a detailed outline of internationally competitive activity the company proposes to undertake under the extended scheme. Continuing participants will not be required to meet the entry requirements for new entrants if they have met all their performance requirements under the 1988 guidelines and the 1990 revised guidelines.

However, to continue to receive factor (f) price increases, these companies will be required to demonstrate their continuing commitment to expanding internationally competitive activity by meeting negotiated performance targets or milestones. Continuing participants in the scheme will maintain their existing base year.

Where a company participated in factor (f) prior to 1 July 1992 and did not meet its performance requirements under the scheme, its eligibility criteria and base year for the extended factor (f) scheme will be negotiated with the Authority, subject to approval by Ministers, based on the company's proposed activity for the extended scheme and its actual performance under past guidelines.

The Authority will evaluate the proposals of all continuing participants to determine whether:

- the company is substantially increasing its level of production and research and development activity in Australia;
- the company's proposed performance targets reflect the increased activity proposed by the company;
- the proposed activity is internationally competitive; and
- the proposed activity will produce significant net benefits for Australia.

If the Authority considers a proposal is insufficient when measured against these criteria, it will discuss additional activity or higher performance targets with the company.

If the Authority determines the proposal is acceptable, it will discuss with the company the payment rate it will recommend to Ministers for approval of the proposal.

Calculation of price increases

Price increases will be calculated on the value of increased activity by the company. The *maximum* payment rate a company may receive for a proposal will be 25% of the value of the increased activity. The actual level of payment will be based on the Authority's assessment of the benefits to Australia of a proposal.

- **Production**

Price increases for production activity will be paid on the increase over the base year in value added in Australia. The rate will vary up to a maximum of 25% of increased value added in Australia.

- **Research and development**

Price increases for R&D activity will be paid on the increase over the base year in after tax expenditure on R&D. The maximum payment rate a company may receive for R&D activity will be 50% of the increase in after tax expenditure, or 25% of the increase in total expenditure, whichever is the lesser.

Application of price increases

Companies may apply price increases under factor (f) to any of their pharmaceutical products listed on the Pharmaceutical Benefits Scheme with the agreement of the Authority. Price increases will be paid direct to companies based on the activity they identify in quarterly activity reports. Payments will be made one quarter in arrears of reported activity.

Maximum price increase

Factor (f) price increases may not increase the price of a product to more than the average price of the product in the European Community (EC). The EC average price will be based on a simple average of the price of the product in EC countries in which it is sold. Where a realistic EC comparison is not possible, the Authority will determine an appropriate price ceiling.

Performance monitoring

The Authority will monitor the performance of all companies receiving factor (f) price increases to ensure price increases paid to companies are consistent with the actual performance of each company.

Companies will be required to submit an annual monitoring report within three months of the end of their financial year in accordance with monitoring guidelines determined by the Authority. Payments of price increases will be based on activity reported by companies in quarterly activity reports and annual monitoring reports.

Three year review

The Authority will review the performance of each company after three years in the factor (f) scheme. To assist the Authority with its review, companies will be required to submit revised forecasts of activity for the remaining years of the scheme. The review will enable the Authority and companies to review their performance in the scheme and to negotiate revised performance levels and price increases for the remainder of the proposal.

The three year review will not preclude companies from lodging new or supplementary proposals. A company's proposed activity may also be subject to review at any time if performance monitoring establishes a company is performing significantly below forecast target levels.