

**AUSTRALIAN FEDERATION OF
AIDS ORGANISATIONS**



**SUBMISSION TO THE
INTERDEPARTMENTAL REVIEW
OF THE
PHARMACEUTICAL BENEFITS SCHEME**

10 July 2002

Section 1: Introduction

The Australian Federation of AIDS Organisations

The Australian Federation of AIDS Organisations (AFAO) is the peak body established in 1986 to represent Australian HIV community based organisations at the national level. AFAO's members are the State and Territory AIDS Councils, the National Association of People With HIV/AIDS, the Australian IV League representing injecting drug users, and the Scarlet Alliance representing sex workers.

AFAO's work focuses on:

- HIV policy advice to national government and to community
- Skills building activities for HIV educators and other health professionals
- HIV prevention and positive education and health promotion campaigns – particularly innovative approaches – with homosexually active men
- Work with Indigenous communities with a focus on HIV and sexual health with gay men and transgender/sistergirls
- Assisting community groups and governments in the Asia/Pacific region
- Vaccines – partner in Australian Vaccine initiative, with funding from the US National Institutes of Health

AFAO is funded primarily by the Department of Health and Ageing, and other sources of funding include the US National Institutes of Health and private donations.

AFAO's interest in pharmaceuticals policy

The advent of effective combination antiretroviral therapy for HIV infection in 1996 has had a profound impact on the HIV/AIDS epidemic in Australia. Many people living with HIV today would not be alive if not for subsidised access to pharmaceuticals, and the decline in the annual number of deaths following AIDS in the second half of the 1990s was due in significant part to the development and availability of treatments for HIV infection.¹ Notwithstanding these benefits, informal indicators both here and in the United States suggest that the trend is reversing, and the limitations of currently available HIV treatments are becoming apparent. There are substantial problems with treatment related toxicities, resistance and cross-resistance, and the impact is being seen in quality of life, morbidity and mortality. For these reasons, people living with HIV/AIDS will continue to have a strong interest in the development and approval of new treatments for HIV infection and associated conditions.

AFAO has played an active and constructive role in advocating for improvements to Australia's drug approval and funding mechanisms, including a submission to the Baume Review in 1991. We are one of only three organisations recognised under the *National Health Act 1953* and Regulations for the purpose of nominating candidates for the position of consumer representative on the Pharmaceutical Benefits Advisory Committee. AFAO is committed to maintaining an active role in advocating for improvements to Australia's drug approval and funding mechanisms.

¹ National Centre in HIV Epidemiology and Clinical Research. *HIV/AIDS and related diseases Annual Surveillance Report 1997*, at p.30.

Scope of this submission

AFAO's position on issues concerning the PBS is being developed over time, reflecting the outcome of discussions both within and outside our organisation, and consultation with other health groups. This submission has been prepared in a very short time, and the themes covered in this submission will be the subject of further work by AFAO, and we expect to develop additional policy positions over time.

Section 2: the increasing cost of Australia's pharmaceuticals

The cost of HIV drugs

HIV antiretroviral drugs, funded under section 100 of the *National Health Act 1953*, are currently estimated to cost around \$78 million per annum. This is around 0.5 percent of the annual cost of all drugs currently funded under the Pharmaceutical Benefits Scheme.

The Highly Specialised Drugs Program (HSDP) continues to be an efficient and effective means of providing life-saving HIV antiretroviral drugs to people living with HIV/AIDS, and to other people with complex and life-threatening medical conditions. A 1999 review of the HSDP² found that there are cost-efficiencies in the scheme compared with the main section 85 list of drugs, because drugs dispensed under the HSDP by-pass drug distributors and retail pharmacists. The report of the review stated:

The Commonwealth has achieved good cost efficiencies with the management of this program. A number of program efficiencies are evident in relation to the drugs funded under alternate mechanisms such as section 85 (the general schedule of benefits) of the PBS. Wholesale margins, mark-ups, dispensing fees and an administrative fee to the States are not currently paid under this program.³

The review found that if drugs under the HSDP were dispensed in the same way as other PBS-funded drugs then there would be an increase in expenditure of approximately 8 percent or (at that time) \$14 million per annum.

Overall costs of the PBS

Expenditure on the PBS is growing rapidly, and since the early 1990s has grown at nearly 14 percent per annum⁴. In 2000-2001, the cost to the Commonwealth Government of the PBS increased by around 20 percent, to over \$4 billion⁵.

These figures may seem alarming, but they do not represent a "crisis" in PBS funding, for several reasons.

Firstly, the price of pharmaceuticals in Australia is low by comparison with prices in other comparable countries. Research by the Productivity Commission in 2001 showed that despite a decade of increasing PBS expenditure, the prices paid to manufacturers for PBS-listed pharmaceuticals in Australia are much lower than the prices paid for the same pharmaceuticals in the United States, Canada, the United Kingdom and Sweden. Australian prices for pharmaceuticals are approximately the same as prices paid in Spain and New

² Department of Health and Family Services. *Review of the Highly Specialised Drugs Program*, Canberra, 1999.

³ At p. 1.

⁴ Senator the Hon Kay Patterson. *Fact Sheet 1: Securing the future of the Pharmaceutical Benefits Scheme*, 14 May 2002, p1.

⁵ Productivity Commission. *International Pharmaceutical Price Differences*, Research Report, July 2001, p.xvi.

Zealand.⁶ The Productivity Commission found that it was difficult to identify robust specific explanations for the price differences, and suggested that they were probably due to a combination of factors which include differences in health systems, subsidy and cost containments mechanisms, market conditions, and production costs. However the Commission found there was some evidence to support the view that Australia's cost-containment arrangements have contributed to keeping prices relatively low.

Secondly, the proportion of GDP which Australia spends on pharmaceuticals is lower than the average for OECD countries. In 1995, Australia's public expenditure on pharmaceuticals was 0.5 percent of GDP, which was less than the average for other OECD countries for which data was available for that year⁷.

Some of the factors which have contributed to the increasing cost of the PBS are likely to be one-off rather than ongoing drivers of increasing cost. For example, in the 2001-2002 Federal Budget the income limit under which self-funded retirees are entitled to a Commonwealth Seniors Health Care Card was increased from \$25,000 to \$50,000. The change is estimated to increase the number of people holding Commonwealth Seniors Health Care Cards by 50,000, resulting in an increased cost to the PBS of approximately \$70 million in 2001-2002⁸. This factor will not produce cost increases of the same magnitude in future years. However in many cases the cost driver will be technology, with varying numbers of newly developed drugs coming on line from year to year.

In addition to the factors above, the Federal Treasurer has referred to the potential impact of an ageing population on the cost of the Pharmaceutical Benefits Scheme⁹, and has proposed a reduction in spending on the PBS to counteract demographic and other factors which tend to increase the cost of the PBS¹⁰. However long-term projections of the kind contained in the *Intergenerational Report* are always likely to be inaccurate to some extent. Some commentary on the report suggests that long-term projections of the kind it attempts to make are not capable of the degree of accuracy the report claims¹¹.

While it is clear that the Australian population is ageing, it is less certain that the ageing population will be the most significant driver of cost increases in the PBS in future. In 1998 the National Centre For Social and Economic Modelling (NATSEM) at the University of Canberra used economic modelling to examine the potential effect of the ageing of Australia's population, the continuation in the upward trend in PBS medicine costs, and the possible impact of a general improvement in Australians' health leading to lower rates of use of prescription medicines. NATSEM concluded that increases in drug prices are likely to have the greatest impact on the cost to government of the PBS, and population ageing the least impact. NATSEM also found that improvements in Australians' health have the potential to significantly limit PBS cost increases¹².

⁶ Ibid.

⁷ OECD Health Data 2002 Table 10: Total expenditure on health, %GDP. www.oecd.org/EN/statistics. Note that Australian data was not available for years after 1999.

⁸ Senate Estimates, Community Affairs Legislation Committee: Health and Ageing Portfolio, February 20 2002, p. 40. Cited in *The Pharmaceutical Benefits Scheme: Options for Cost Control*. Information and Research Services, Parliamentary Library, Canberra, May 2002, at p. 5.

⁹ See Commonwealth of Australia. *2002-2003 Budget Paper No. 5: Intergenerational Report 2002-2003*. www.budget.gov.au/2002-03/bp5/html/01_BP5Prelim.html#P42_796.

¹⁰ *Intergenerational Report*, *ibid.* Part III: *Projections for Spending and Revenue – Health and Aged Care*.

¹¹ See for example The Weekend Australian Financial Review June 22-23, 2002, at p4: *Treasury PBS forecasts attacked*.

¹² Walker A, Percival R, and Harding A. *The Impact of Demographic and Other Changes on Expenditure on Pharmaceutical Benefits in 2020 in Australia*. www.natsem.canberra.edu.au/pubs/dps/dp31/dp31.html.

The PBS is cost-effective

AFAO acknowledges that expenditure on the PBS comes either at the expense of other government programs, or at the expense of taxpayers, or both. We support sensible and cost-effective expenditure in this as in other government programs. However, if it is found that paying for pharmaceuticals is cost-effective for society as a whole and good for the community, then the cost of the PBS is irrelevant. In fact, if pharmaceuticals provide worthwhile benefits for the community, then the growth in expenditure on the PBS should be celebrated, as greater use of pharmaceuticals is saving the community money in other areas of health spending, and increasing quality of life.

HIV antiretrovirals have made a fundamental difference to the lives of many people living with HIV/AIDS, who are able to live healthier and happier lives. Many people who could not work before now can, and pharmaceuticals allow many people to make a fuller contribution to society. These benefits are currently not properly considered in decisions on whether to subsidise drugs through the PBS.

Section 3: How to improve the effectiveness of the PBS

AFAO proposes changes in four areas which would improve the effectiveness and efficiency of the PBS.

1. Greater involvement of consumers

Currently there is a single consumer representative on each of the Pharmaceutical Benefits Advisory Committee and the Pharmaceutical Benefits Pricing Authority. Apart from these consumer positions, there is no recognised procedure by which the community can contribute to decision-making regarding the listing of drugs on the PBS. Consumer representatives cannot consult with the community in relation to deliberations of the respective committees due to the secrecy requirements of the *National Health Act 1958*. The community should play a greater role in decisions affecting the PBS, and this can be achieved by increasing the number of consumer representatives on PBS committees, and by implementing a system for public submissions on matters which come before the committees.

Consumers can provide additional information that is valid and valuable when considering subsidised access to new drugs. In particular, people living with HIV/AIDS are likely to be able to provide information on such things as:

- Quality of life issues such as side effects, pill burden, timing of doses;
- Current drug treatments available for particular illnesses and benefits and problems associated with such treatments;
- Benefits and risks to consumers of the new medicine such as adverse reactions or increased efficacy compared with currently available medicines;
- The information that consumers will require about the new medicines
- The public health implications of new medicines.¹³

In order to be able to provide this input, applications for PBS listing by pharmaceutical manufacturers should be advertised, and the community should be invited to make submissions in relation to these matters. A concern which might be raised in relation to this proposal is that the community is susceptible to drug company marketing, or that

¹³ Consumers Health Forum. *Consumers input to Australia's drug evaluation process – Information for voting members and consumer representatives, March 2002.*

community members without a scientific background will find it difficult to distinguish between high-profile studies and genuinely good research. However AFAO and many other community groups have developed expertise in pharmaceuticals policy, which have been demonstrated through our contributions to a range of national policy forums.

Recommendation

PBS committees should solicit submissions from the community on applications which come before them.

Other national committees to which AFAO provides representatives, such as governmental advisory committees and committees of the National HIV Research Centres, provide for at least two community representatives on each committee. This practice recognises the role that peer support plays in enabling all committee members to contribute to the committees' work, and should also apply to PBS committees. The appropriate number of community representatives on a committee will depend in part on the size of the committee, but the level of community representation on PBS committees should be reviewed and increased where appropriate.

Related issues concerning community representatives on Pharmaceutical Benefits Branch committees which need to be addressed include:

- Clear statements of roles and responsibilities for committee members;
- The removal of unreasonable legislative constraints on committee members effectively performing their roles and responsibilities;
- A process for submissions from the community on matters which come before committees;
- Adequate resourcing of committee members;
- Where there is only one community representative on a committee, consideration should be given to appointing a deputy for that representative to assist the main representative.

Recommendation

Community representation on Pharmaceutical Benefits Branch committees should be reviewed and increased where appropriate.

2. Assessing the cost and benefit of a drug

The costs of the PBS are transparent and clearly quantified. However, benefits are not as clearly defined or quantified as the scheme currently operates. Some of these benefits include:

- Less call on Federal Government programs such as social security and other health programs, and greater tax revenues;
- Less pressure on public hospitals and consequently, state and territory government revenue;
- Trickle down effects of more spending in the community — if more people work, then more money is being spent at the local shopping centre, driving economic growth;
- Reduced tax burden on all taxpayers as more people are paying tax and less are being supported through social security and other income support such as superannuation;
- Individuals on pharmaceuticals can in some cases have a better quality of life and greater independence. Some people are able to move from a low income (and in some cases, poverty) to having a reasonable income.

AFAO believes that the benefits of public spending on pharmaceuticals are significant, and are not properly taken into account when the cost of the PBS is considered. An example of a more comprehensive approach is the analysis performed by Access Economics in relation to the management of rheumatoid arthritis in juveniles and adults, using the drug etanercept (Enbrel)¹⁴. The researchers identified three types of costs associated with diseases such as Rheumatoid Arthritis and Juvenile Chronic Arthritis:

- **Direct costs:** these are the financial costs to the Australian health system, and include the cost of running hospitals and nursing homes (buildings, nursing, consumables), GP and specialist services reimbursed through Medicare and private funds, the cost of pharmaceuticals (PBS and private), and of other medications, allied health services, research and other “direct” costs (e.g. health administration);
- **Indirect financial costs:** these include income forfeited due to sickness and early retirement, equipment, modifications and special education costs, and the cost of care (often provided on a voluntary basis by spouse or other family member, but an economic cost nonetheless); and
- **Non-financial costs from loss of healthy life:** pain, loss of quality of life, and premature death¹⁵.

The researchers concluded that the direct health system costs are merely the tip of the iceberg, and that where there are direct cost savings then there will be a multiplicity of greater indirect savings as well. They state:

Too often the rather myopic view is adopted that pharmacological costs must necessarily be contained in order to reduce health system costs. Clearly, the big picture shows that dollars spent on effective drugs which prevent and control disease will ultimately benefit not only the individuals who would suffer and die from those diseases, but also the economy.¹⁶

Recommendation

Direct and indirect costs, and the non-financial costs of loss of healthy life, should all be considered when making decisions about spending on pharmaceuticals, to ensure that all of the benefits to the individual and to the community are properly taken into account in decisions about funding pharmaceuticals.

3. Making processes more transparent

The procedures by which drugs are considered for listing on the PBS, and decisions as to listing, should be made more open and transparent to the general public. The quality of decision-making by the PBAC can be improved by having a broader range of input than is currently received. Greater transparency in relation to PBAC decisions can also serve an important information and education role for consumers and prescribers, who currently rely almost exclusively on information provided by pharmaceutical manufacturers to find out about newly approved (or rejected) medicines. Short summaries of recommendations to list drugs appear on the Pharmaceutical Benefits Branch website, but fuller disclosure of recommendations to list or not to list drugs should be made.

¹⁴ Access Economics Pty Ltd. *Rheumatoid Arthritis Management in Adults and Juveniles: Direct and Indirect Costs of Anti-TNF Therapy in Australia*. Canberra, February 2002.

¹⁵ At p. 13.

¹⁶ At p. 28.

Greater transparency in PBAC processes will require amendment of the *National Health Act 1953*, which currently requires PBAC members and departmental officers to protect commercial-in-confidence material.

Recommendation

The *National Health Act 1953* should be amended to permit departmental officers and committee members to disclose information regarding decisions of PBS committees.

4. Improving the timeliness of approval processes

Notwithstanding improvements over the last decade in the timeliness of the Pharmaceutical Benefits Branch's processes, in some cases access to new drugs is still subject to unwarranted delays. Delays have meant that the standard of care provided to Australian patients is compromised, including in relation to the treatment of serious life-threatening conditions. An example is the delay in approving the drug Caelyx¹⁷, manufactured by Schering-Plough and used to treat the AIDS-related cancer Kaposi Sarcoma. This drug was approved by the United States Food and Drug Administration in May 1996, but was not listed on the PBS until over two years later. There was abundant evidence of the superior therapeutic efficacy of Caelyx over other treatments for Kaposi Sarcoma available at the time, together with evidence of markedly improved quality of life for those people taking the drug, due to its ability to reduce or completely eliminate the disfiguring Kaposi Sarcoma skin lesions.

The delay in approving Caelyx created an additional burden of suffering for many people living with HIV/AIDS. It also placed pressure on the compassionate access scheme that Schering-Plough had established to provide some access prior to the drug being granted PBS approval, and is a likely factor contributing to the greater difficulty now experienced by HIV patient groups in negotiating compassionate access to new drugs.

A number of recommendations aimed at improving the timeliness of PBS processes were made as a result of the review of PBS listing processes by the then Parliamentary Secretary for the PBS in 2000¹⁸, but in the main these do not appear to have been acted upon. Of particular note is the review's recommendation that the Pharmaceutical Benefits Branch and the TGA develop an integrated arrangement to accelerate the listing process for drugs considered to warrant fast-tracking¹⁹.

At present the Federal Cabinet is a source of delay in having new drugs listed on the PBS schedule. Four drugs for which pre-Cabinet approval procedures were completed early in 2002 require cabinet approval as they are each estimated to cost more than \$10 million per year. These drugs have been awaiting Cabinet approval since May 2002²⁰. Delays of this nature can compromise the standard of health care provided to Australians, and should be avoided.

Recommendation

Processes should be reviewed in order to address the significant delays which occur from time to time as a result of Cabinet considering approval of new drugs on the PBS.

¹⁷ Pegylated liposomal doxorubicin hydrochloride

¹⁸ Commonwealth of Australia. *Final Report of the Review of PBS Listing Arrangements by Senator Tambling Review Committee*, Canberra, 2000.

¹⁹ At p. 5.

²⁰ The drugs which have been approved by PBAC and PBPA, which are currently awaiting Cabinet approval are: Singular (montelukast) – Asthma medication for children aged 2-14 years; Avandia (rosiglitazone) and Actos (pioglitazone) – for Type 2 non-insulin dependant diabetes; Spiriva (tiotropium bromide) – oral inhalation capsule for chronic obstructive pulmonary disease.

Section 4: paying for the PBS

A number of measures have been suggested with a view to reducing PBS expenditure, and limiting demand for prescription drugs, particularly new and expensive drugs. These include increased co-payments, reducing subsidised access to “non-essential” drugs, increasing the role of private health insurance in funding prescription drugs, setting budgetary limits to GP prescribing, a flat monetary levy on all Australians to finance new drugs, minimising inappropriate prescribing, and managing leakage.

If it is found that paying for pharmaceuticals is cost-effective for society as a whole, then the size of the PBS budget is not relevant. Expenditure on the PBS *per se* should not be viewed as problematic, but AFAO does support responsible expenditure of public funds by government, and we do support cost containment measures which improve the cost-effectiveness, properly assessed, of the PBS. Cost containment measures are only justified if they do not compromise key features of the scheme: *comprehensiveness* (i.e. the range of medicines available are the medicines that Australians need, at the time they need them); and *universality*: all Australians have access on the basis of need, rather than on the basis of their capacity to pay.²¹

AFAO does not propose to provide a detailed analysis of all possible cost-containment measures, but makes the following comments on some proposed measures:

Reducing leakage

Leakage involves the greater than originally estimated market uptake of a drug²², and can occur where a manufacturer promotes use of its drug outside of the indications for which a PBS subsidy was agreed to²³. The effect of an unexpected higher volume of prescriptions of a drug is compounded when a price-volume agreement which might otherwise have determined a lower cost per unit of the drug at the higher volume is not negotiated with the manufacturer.²⁴

Leakage should be addressed by providing support for quality prescribing by doctors. AFAO is opposed to overly rigid and formulaic control of prescribing, or undue interference in the doctor-patient relationship. In particular, AFAO does not support the “registry” model recently proposed by the National Centre for Social and Economic Modelling²⁵, because it has the potential to create unacceptably rigid and harsh conditions of entitlement to subsidised drugs. Imposing stringent conditions on when a doctor may or may not prescribe a particular drug poses a threat to the quality of healthcare that Australian patients receive. The human body is complex and cannot be subjected to overly standardised approaches, particularly for people with chronic and life-threatening conditions.

Recommendation

The registry model should not be adopted as a means of dealing with the problem of leakage.

²¹ Commonwealth of Australia. The Pharmaceutical Benefits Scheme: Options for Cost Control, May 2002, p.11.

²² *Ibid*, p.19.

²³ Birket D, Goddard M, and Henry D. *Costs and benefits: securing the future of the Pharmaceutical Benefits Scheme*. March 2001, at p4.

²⁴ Commonwealth of Australia, *op. cit.* at p.19.

²⁵ National Centre for Social and Economic Modelling. *Funding of High Cost Biotechnology and Other Innovative Targeted Therapies under the Pharmaceutical Benefits Scheme*, February 2002, pp33ff.

More transparent PBS processes would provide additional information to both doctors and patients concerning new drugs and the indications for which they are subsidised. A comprehensive and publicly available cost-benefit analysis will provide enough information to health practitioners to render a complex administrative system largely redundant, as medical practitioners will have high quality information available on which to base prescribing decisions, rather than being forced to rely on pharmaceutical company information.

The PBAC should be resourced to conduct its own research in order to make independent estimates of the likely uptake of a new drug. This will assist the PBAC to reduce its reliance on the estimates of uptake made by pharmaceutical manufacturers. Unforeseen costs resulting from estimates of uptake falling significantly below actual uptake can be minimised by greater use of price-volume agreements, which provide for a lower price per prescription once the volume of prescriptions in a year reaches a certain level. Where significant leakage is thought likely or possible, a price-volume agreement can be used to contain the cost.

Increased co-payments

Increases in the co-payment required of consumers who are prescribed PBS-subsidised medicines have an unduly harsh impact on people living with HIV/AIDS, many of whom live in poverty. The *HIV Futures 3* report²⁶ found that almost half the respondents (48.7 percent) rely on a government pension or benefit as their main source of income²⁷, and almost one third (31.3 percent) are living below the poverty line²⁸. Substantial proportions of respondents rated food, clothing, utilities and rent as very difficult to afford²⁹. For those people living below the poverty line, one quarter rated paying for medical services as very difficult, over 28 percent rated paying for food as very difficult, and over 53 percent rated paying for clothing as very difficult³⁰.

Any increase in co-payments places an additional burden on low-income earners. People living with HIV/AIDS are not the only people who would suffer hardship if the patient co-payment was increased, as 80 percent of PBS beneficiaries are concessional³¹. In these circumstances, increasing co-payments has limited potential to offset PBS costs. Furthermore it is undesirable to increase co-payments because there is evidence that increases in co-payments can result in patients not filling their scripts, which threatens the benefits that accrue to the community through use of pharmaceuticals, in particular by deferring health care costs that will eventually be borne by other areas of the health care system³².

Recommendation

Increases to co-payments should not be used as a means of limiting increases in PBS costs, unless it can be shown that such increases will not result in further hardship to consumers, and will not result in deferred health care costs that will be borne by other areas of the health care system.

Encouraging appropriate prescribing

²⁶ Grierson G, McDonald K, Misson S, O'Brien M, and Pitts M. *HIV Futures 3: Positive Australians on Services, Health and Well-Being*. The Living With HIV Program at the Australian Research Centre in Sex, Health and Society, La Trobe University, Melbourne, May 2002.

²⁷ *Ibid.* at p.100.

²⁸ *Ibid.* at p.103.

²⁹ *Ibid.* at p.99.

³⁰ *Ibid.* at p.104.

³¹ Commonwealth of Australia 2002, *op. cit.* at p.13.

³² *Ibid.* at p.13.

AFAO supports initiatives which enhance the quality of doctors' prescribing practices, such as the National Prescribing Service. This service has achieved improvements in prescribing practices which have also contributed to containing the costs of the PBS³³. Improvements in the quality of prescribing need to be fostered through education, information and support to doctors. Detailed information about the reasons for decisions made by Pharmaceutical Benefits Branch committees should be available to doctors making prescribing decisions.

Recommendation

Appropriate prescribing should be supported through ongoing provision of resources to the National Prescribing Service and through greater transparency of Pharmaceutical Benefits Branch decision-making.

Re-assessing the prices paid for listed drugs

In 1997 the Australian National Audit Office recommended that improvements be made to mechanisms for reviewing the prices paid for drugs on the PBS, to ensure that the prices agreed with manufacturers remain valid³⁴. The ANAO stated:

If the government is to realise economies as older drugs become comparatively less effective (and companies have succeeded in recouping their development costs), there may be scope to adopt a more active approach in the price revision process³⁵.

The ANAO found that most proposed revisions were the result of manufacturers' requests for price increases, and that the process depends on suppliers making requests for review. A mechanism needs to be established to enable the PBPA to regularly review the prices of all drugs on the PBS, with priority given to reviewing the prices of those drugs which were listed prior to the introduction of cost-effectiveness requirements. The prices of all drugs should be reviewed at least every 10 years, to ensure that the prices remain valid.

Recommendation

A mechanism should be established to enable the PBPA to regularly review the prices of all drugs on the PBS, with priority given to reviewing the prices of drugs listed prior to the introduction of cost-effectiveness requirements. The PBPA should review the prices of all drugs at least every 10 years.

In addition to cost-containment measures, the Federal Government should also consider options for increasing revenue to fund additional expenditure on the PBS, including through the taxation system.

Taxation

In addition to considering possible measures for cost-containment, increasing taxation revenue to support the PBS in particular and the health system in general, is an option which deserves full debate and consideration.

Recommendation

Increasing taxation revenue to fund the PBS in particular and the health system in general should be considered.

³³ Commonwealth of Australia 2002, *op. cit.* at p.11.

³⁴ Australian National Audit Office. *Pharmaceutical Benefits Scheme* (Auditor-General Performance Audit Report No. 12, 1997-98). ANAO, Canberra, 1997.

³⁵At pp. 58-59.

Section 5: conclusions

1. The Pharmaceutical Benefits Scheme is not in crisis

The Pharmaceutical Benefits Scheme is not in crisis. It is not clear that the recent increase in the rate of growth in PBS expenditure will continue. Several factors which have contributed to recent growth, such as the listing of certain drugs, are clearly one-off phenomena. Other factors such as the ageing of the Australian population may have less of an impact on the cost of the PBS than is assumed. Australia's expenditure on pharmaceuticals as a proportion of gross domestic product is less than the average for OECD countries, and the prices paid to manufacturers for pharmaceuticals is also low by comparison with most other OECD countries.

2. The Pharmaceutical Benefits Scheme can be improved

Changes can be made to PBS processes which will improve the efficiency and transparency of the scheme.

Greater community involvement can be fostered through informing the general community about applications coming before Pharmaceutical Benefits Branch committees, and inviting submissions. Community representation on Pharmaceutical Benefits Branch committees should be reviewed and increased where appropriate. There should be better resourcing of community members on Pharmaceutical Benefits Branch committees.

Broadening the factors which are taken into account in assessing the cost-effectiveness of a drug will result in a more accurate assessment of the benefit of a drug to individuals and the community as a whole.

Priority should be given to applications in relation to drugs for serious life-threatening illnesses, and the problem of delays caused by drugs awaiting Cabinet approval must be resolved.

3. Cost containment measures

Many of the cost-containment measures which have been proposed have the potential to compromise the effectiveness of the PBS in achieving timely, reliable and affordable access for the community to necessary medicines. Some cost containment measures can be implemented which will improve the effectiveness of the PBS. These will mainly involve better support to doctors for quality prescribing and applying cost-effectiveness requirements to all drugs on the PBS. The option of increasing taxation to pay for the PBS and the health system in general should be considered.