

And on the cover of the Guide were two words in red - Don't Panic

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The advice given to travellers by The Hitchhikers Guide to the Galaxy is probably worth noting by those that are concerned about the future of the Pharmaceutical Benefit Scheme (PBS) and the Pharmaceutical Benefits Advisory Committee. Don't panic. The traveller would, however, be prudent to consider not only under what circumstances the Panic Button should be pushed, but also what are some of the alternatives to pushing the button.

Recent changes to the membership of the Pharmaceutical Benefits Advisory Committee (PBAC) have raised alarm amongst academics, health professionals, the media and others interested in equity and efficiency in the health sector, and in the processes of good government.

To an outsider, the dismissal of such a distinguished and expert group from the PBAC was ineptly handled and appeared to be tinged with personal animosities. But the process for managing important national committees does not seem to be a priority for this Government - consider the fact that the NHMRC has almost ceased to operate during two periods of its term.

We have assertions from the Government that, except for the inclusion of a former lobbyist for the drug industry, the PBAC will continue to operate as before - under the same guidelines and with the same processes. Whether the former industry lobbyist will act as "poacher turned game-keeper" or, as some people apparently fear, will act in a partisan manner within the Committee has yet to be seen. Unfortunately, coming from a Government that promised to maintain Medicare, these assurances have not convinced many people that the PBAC changes do not presage a shift towards the interests of the drug industry.

However, given the current circumstances, is it likely that there could be a sell-out to the industry? With an election coming up, with a budget surplus (or is it a deficit?) to protect, and with multi-national corporations being on the nose with many in the Australian electorate - how likely is that that this (or any) Government would want to provide the drug industry with some sort of windfall gain in the short term or in the medium term? The Commonwealth Government funded 83% of PBS expenditure in 1999-2000 (up from 78% in 1991-92) so any sell-out would significantly harm the budget.

This paper suggests that while the current PBS processes have served the community well, it may be necessary in the not too distant future to consider changes to the present arrangements both to the PBS and to the broader environment in which it operates. I will give a selective review of the history of the PBS and its processes to put the discussion in context.

An overview of the history and processes of the PBS

The PBS developed out of a 1944 proposal to provide a program of "... life saving and disease preventing drugs ... free of charge to the whole community" as part of a national health scheme. The Australian Medical Association (then British Medical Association) successfully challenged the program in the High Court, which declared some sections of the program to be unconstitutional. A referendum changed the constitution to enable the scheme to continue, and a further successful challenge to the High Court by the medical profession stalled the program again. Following the change of government in 1949, a slightly modified scheme started to operate.

Since its inception the PBS has been seen as a leader in a number of ways: during the 1950s it was one of the few “free” drug programs available to an entire population. During the 1970s when cost containment was the major concern of most health systems, the PBS gained a reputation amongst health policy makers for being effective in controlling drug costs. Since the 1990s, it has been seen as a leader in introducing the requirement that drugs should be evaluated for cost-effectiveness, as well as safety and efficacy, and that cost-effectiveness should be considered in setting prices for new drugs. The roles of the Australian Drug Evaluation Committee and the Therapeutics Goods Administration, in ensuring the safety of drugs marketed in Australia, has contributed to Australia's reputation as having a first class national drug program.

This does not mean that there have been no problems with the PBS. During the 1960s, drug prices in Australia were relatively high by world standards. For most of the 1960s, expenditure on prescribed drugs in Australia was over 14% of total health expenditure and 0.75% of GDP (Deeble 1978).

By the mid-1970s, the situation had changed dramatically. Drug expenditure accounted for only 7.7% of recurrent health expenditure and 0.6% of GDP (Deeble op cit). This was due to a combination of several factors. Implementation of some of the recommendations of the Report of the House of Representatives Select Committee on Pharmaceutical Benefits (1973) strengthened the Department of Health's capacity to negotiate drug prices. Also there was a slowing in the rate of introduction of new patented drugs and an increase in the number of high cost/high use drugs coming off patent. By the mid-1970s, it was often quoted that Australian drug prices were 55% of world average prices.

In 1998-99, prescribed drug expenditure had increased to about 8.5% of total health expenditure and about 0.72% of GDP (AIHW 1999). This probably underestimates the actual amount a little, since a number of drugs formerly only available on prescription are now available as over-the-counter drugs and are not counted in the estimate of expenditure on prescribed drugs.

The PBS has also experienced several surges in expenditure that caused anxiety. During the early 1990s, following the introduction of ACE inhibitors (hypertension lowering drugs) and some of the ‘Statins’ (serum cholesterol lowering drugs), total expenditure (government plus patient contribution) under the PBS increased by about 20% a year in two successive years, before falling to 7-8% a year during the late 1990s. It is not known whether the cost-effectiveness information that was becoming available to the PBAC allowed the PBS through the Pharmaceutical Benefit Pricing Authority (PBPA) to reduce the rate of increase of PBS expenditure. However, PBS expenditure started to accelerate during the late 1990s and it increased by 13% from 1998-99 to 1999-2000. It is reported to be increasing even faster following the recent listing of Celebrex and other new drugs.

While the capacity of the PBS to control prices is often seen as a “good thing” by health policy analysts, the pharmaceutical drug manufacturers and the Department of Industry, Science and Resources have not seen it this way. As a consequence, there were several inquiries into the drug industry and the PBS.

The Ralph Inquiry in 1979, the Industry Assistance Commission in 1985, and the Industry Commission 1996 all focussed on the PBS/pharmaceutical drug manufacture interface to a greater or lesser extent. The Pharmaceutical Industry Development Program was adopted by the Commonwealth Government in 1987 “... to encourage the growth of the pharmaceutical industry in Australia” (Industry Commission 1996). The Development Program provided direct funding to pharmaceutical drug manufacturers who undertook research and development in Australia. The PBPA was required to take into account nine factors in recommending prices of drugs to the Minister for Health. The 5th factor that the PBPA was required to consider was “... the level of activity being undertaken by the company in Australia, including new investment, production, research and development” and the Pharmaceutical Industry Development Program became known as the Factor ‘f’ program. This has been superseded by the Pharmaceutical Industry Investment Program which is similar to Factor ‘f’ and still requires the PBPA to consider the level of a pharmaceutical drug manufacturer's R and D activity when determining prices.

The inter-relationship between the PBS role and industry development is further spelled out in the National Medicinal Drug Policy, which has four essential components:

1. the supply of medicines of established and acceptable quality, safety and efficacy;
2. timely, reliable and affordable access by the community to necessary medicines;
3. the quality of use of the medicines by health care providers and consumers; and
4. the maintenance of a viable pharmaceutical industry.

This requirement to consider the interests of industry development makes the already complex task of the PBAC even more difficult.

An overview of the PBS processes

The PBS processes are described in detail on the Department of Health and Aged Care website www.health.gov.au:80/hfs/haf/docs/pharmpac/part1.htm. In short, the key steps are as follows:

- ADEC recommendation and/or TGA registration granted
- Consideration by the Economics Sub-Committee (ESC) members of the PBAC
- Pharmaceutical Evaluation Section (of DHAC) evaluation plus PBAC secretariat overview of submissions provided to sponsor
- Meeting of Economics Sub-Committee
- Pre-PBAC comments provided by sponsor
- ESC reports plus sponsor comments to PBAC members
- PBAC meeting
- Written advice to sponsor
- Meeting of Pricing Authority
- Approval by the Minister/Cabinet
- Listing in the Schedule.

Limitations of the current system - and some alternatives

The PBS system has many strengths and a few limitations. Some of the limitations are significant, and some are due to the broader health system in which the PBS is located.

One of the system problems arises from the fact that the principal 'delivery system' for the PBS is driven by fee-for-service medical practitioners who are concentrated in cities and in richer parts within cities. This results in an increasing proportion of the health budget being allocated by 'provider-driven' resource allocation formulas and not a population needs basis. There is no simple solution to this problem. One approach could be for the commonwealth allocate **regional population-based PBS budgets** and to allow them to be used to provide other services to the population if the doctor supply is not available, or to develop other methods of prescribing and monitoring drugs. This would be far from ideal, but it would be more equitable than the current arrangement.

A second health system problem is that the PBS is the only part of the Commonwealth-funded health services that has any track record of using cost-effectiveness for allocating its resources. The Medical Services Advisory Committee (MSAC) is now starting to require new services proposed to be funded under the Medical Benefits Schedule to demonstrate relative cost-effectiveness.

Once experience is gained by MSAC, consideration should be given to developing **Health Priority Budgets** from which both drugs, medical services and health promotion activities are funded. This would allow consistent cost-effectiveness criteria to be used in determining the optimal allocation of resources to treat specific health conditions. A theoretical nicety would be to try to equalise the cost-effectiveness ratios (cost per QALY?) used to allocate funds within and across Health Priority Areas, and so approach an efficient allocation of resources across all health services. Not all of the PBS budget could be allocated in this manner as many drugs, such as analgesics and some tranquillisers, may be used across many Areas.

A third issue concerns the use of cost-effectiveness as a criterion in setting prices and allocating resources. The effectiveness measures used in drug evaluation often vary from evaluation to evaluation and so prevent any comparison of cost-effectiveness for drugs used to treat different diseases. Even the greatest supporter of the development and use of such measures as QALYs would have to acknowledge the limits in our ability to make comparisons for different treatments for different diseases. We can be reasonably confident in saying that this drug is more or less cost-effective in treating this condition than is another drug, and therefore concluding that it should have an higher or lower price, but the cost-effectiveness technology does not allow us to go much further than that. Any review of the literature on cost-effectiveness of different treatments for different conditions shows enormous variation in the cost per QALY (or whatever measure of cost-effectiveness is used). No constant cost effective ratio is used in determining resource allocation decisions in the health system.

This does not mean that cost-effectiveness criterion should not be used - far from it. There should be additional resources put into developing and refining of QALY-type measures so that they become more robust.

At present, the PBPA and PBAC have to make judgements as to how much should be paid for new drugs, based on their appreciation of the additional cost-effectiveness of one drug over another. Implicit in this approach is an acceptance that cost-effectiveness is an acceptable measure for making resource allocation decisions. There is much debate as to whether it is ethical or feasible to use these measures for making such judgements. I personally believe that, even with the imperfect measures currently available, the use of cost-effectiveness gives greater transparency to decision making processes, while accepting that other factors will be considered by members of the PBAC and PBPA, as well as the Minister and Cabinet if things get to that stage. Consideration could be given to developing a consumer panel to provide advice and comment to the PBAC and PBPA on some of these issues.

It seems likely that, with the explosion of both new pharmaceutical and bio-medical techniques, there will be an increasing need to have good methods of making just and humane resource allocation decisions, especially in relation to pharmaceutical drugs. At present there are probably few drugs, vaccines, and treatments that provide significant quality of life improvements which are not funded, but this is unlikely to be the case in future. While society may be prepared to pay more than it now pays for health care, there are limits to this. This will mean that, eventually, there will be greater inequities in access to high quality care than we currently have. This situation will probably have to be accepted in the long run, but if we can make the health budget go further than at present, then we can delay the time when it occurs. Reducing the cost of drugs is one way of making the budget go further and this is discussed in the next section.

Are Australia's drugs too cheap for our own good?

This is the title of the editor's introduction to these articles on the PBS. In my view the answer is No. The principal argument in support of this position is that the 'social contract' that underpins the patent system, and that underpins the drug industry in a way that it supports no other industry, is no longer a fair contract. The patent system was developed to provide benefits to the public by giving an inventor a monopoly on exploiting their invention for a defined period, in exchange for the inventor revealing the 'secret' of the invention. Disclosing this secret enabled others to develop even better products and methods. While the Patents Act gives the right to the patentees to 'exploit' the patent, it also talks about 'the reasonable requirements of the public'. In particular, it refers to "... the reasonable requirements of the public with respect to a patented invention are ... taken not to have been satisfied if, or the demand in Australia for the patented product, or for a product resulting from the patented process, is not reasonably met, because of the patentee's failure ... to manufacture the patented product to an adequate extent, and supply it on reasonable terms" (Sec 135)

Why is the balance wrong?

The issue of profitability. This section draws on information on the home page of the US Public Citizens - Congress Watch, and material in <http://www.citizen.org/congress/drugs/factsheets/mostprofitable.htm>. The information here is the most up to date that the author could find, but it is consistent with material produced by the US Federal Trade Commission during the 1970s and 1980s.

In brief, the emotively titled report "Drug industry most profitable again: New Fortune 500 report confirms 'Druggernaut' tops other industries in profitability last year" states that, as in the previous 30 years, the profitability of the Fortune 500 listed drug companies was higher than for any other industry group. Moreover, the difference between the profitability of the drug companies and other sectors continues to grow.

The picture was very much the same whether profit was measured as a percentage of sales or return on equity or assets. For the Fortune 500 drug companies, profit as a percentage of revenue in 2000 was 18.6% compared to the median for Fortune 500 companies of 4.9%, return on assets was 17.7% compared with 3.9%, and return on equity was 29.4% compared with 15.8%. There is an extensive and complex literature arguing how these figures should be interpreted, but from a share investor's point of view they are very much academic arguments. Also, being 'top of the pops' for 30 or 40 years gives an interesting insight into the comparative risk of large pharmaceutical drug companies as compared to other industry groups. Seemingly invincible sectors like the electronics and computer sectors have had their ups and downs, but not the drug industry.

Use of resources. According to the publication 'The Pharmaceutical Profitability Outlook' from Reuters Business Insight (2000), in 1997 the major drug companies spent about 50% more on sales and promotion and development than on clinical drug development. In the absence of any consistent source of data on the internal costs of drug companies, it appears that the pattern of costs is similar to what it was in the 1970s and 80s. 12% of revenue goes to R&D (Fortune 500), 17% goes to profits (Fortune 500) and 18-20% goes to sales and promotion. (The proportion going to RD was probably over stated. The US Congress inquiries into the drug industry during the 1970s considered that some of the R&D expenditure was in the form of clinical trials that were mainly driven by sales and promotion. Similarly, there have been reports from the UK and Australia about inducements to GPs to take part in so-called clinical trials that appeared to be more marketing ploys, not to say inducements to use the new drugs. The R&D to Sales and Promotion ratio may be lower than shown here).

On the basis of international figures, a case could be made for reducing drug prices by 20%. 10% could come from profits, still leaving the industry as profitable if not more so than most other large companies. 10% could come from marketing - it may improve prescribing! This would leave the resources for R&D intact.

The Reuters Business Insight publication asks "Is it viable to outsource all of a company's operations to create a virtual pharmaceutical company?" The Government could consider requiring drug companies to 'outsource' almost all of their promotion and advertising activities - and contract out the provision of these services to universities and the medical profession. Reduction in prices of drugs could be used to partly fund academic and professional education programs, and to partly lower government or consumer expenditures on drugs.

When is enough enough?

The provision of AIDS drugs to the poor countries raises the question as to whether national regulation of patents and multinational companies is effective or whether it is in humanity's interest. The drug industries' response to the South African patents case seems to suggest that for some companies enough is never enough. Several drug companies have made vast profits from the provision of HIV/AIDS drugs to the rich countries which contain only a small proportion of the people suffering from this disease. With one or two exceptions, they seem to be arguing that they want to make similar rates of profit from the poorer countries on drugs on which they will have already recouped their development costs many times over.

The foregoing discussion on profitability is based on international prices and revenues and as such it cannot be transferred direct to the Australian circumstance. The only inquiries into the industry in Australia that generated hard data on which to make judgements about the reasonableness of profits and advertising were House of Representative Select Committee Report (1973) and the Ralph Inquiry (1979).

The data generated for these reports suggested that the advertising costs were similar to those reported above, the amount of R&D expenditure (after including royalty payments) was about 50-65% of that reported above, and profits were less. However, neither inquiry made any attempt to estimate the impact of transfer pricing on profits or indirect R&D - the life blood of the drug industry during the 1960-80s at least. My Master's Degree (Harvey 1974) documented fivefold differences in the prices reported for customs purposes for antibiotics, while in 1970 the British Monopolies Commission into the supply of chlodiazepoxide (Librium) and diazepam (Valium) found that Roche (Switzerland) was selling these products to its UK subsidiary for twenty times what were regarded as arms length prices.

The Ralph data showed quite clearly that comparing Australian prices with overseas prices without adjusting for factor costs was a waste of time. It was only necessary to calculate what contribution Australia would make to parent companies' profits and R&D if we paid world average prices (which was the industry call at that time). Given we already paid the costs of manufacture, administration and promotion in Australian dollars to Australians, the 81% increase in revenues if prices went from 55% to 100% of world average prices meant that we would have been making totally unacceptable contributions (unacceptable to Australians) to either profits or R&D.

Conclusions

The PBS is an effective process that is worth fighting to preserve. However, there are limitations to its effectiveness, due mainly to the current structure for Commonwealth funding of health services, that can and should be addressed.

While the use of cost-effectiveness analysis can make a contribution to determining which drugs should be listed on the PBS and in determining their prices, the final decisions on both listing and prices have to acknowledge the limitations of the current methods. PBS prices will always be determined largely by 'market' forces - a monopolist seller of a patented drug dealing with a monopolist public buyer - the Minister by way of the PBPA.

There is a good case to be made for an inquiry into the drug industry in Australia and into the operation of the Patents Act and how they impact on poorer countries - both for the medium term interests of equity and efficiency in Australia and for the poorer people in the world. It is common that people complain we have too many inquiries. However, the question to ask is not how many inquiries we have had, but whether we have got things nearly right. There is no need for panic, but nor should we be complacent.

While the argument has not been explored here, a case can be made for separating the industry development policy and PBS pricing functions. The Department of Industry, Science and Resources should be responsible for funding pharmaceutical industry development programs, and the PBS should be responsible for getting the best prices for the health consumer. The 'f' clause should be removed from the factors that the PBPA should consider when determining price. This would give a greater degree of transparency to pricing recommendations.

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