EDITORIAL

The Pharmaceutical Benefits Scheme: economic evaluation works ... but is not a panacea

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For most of the first 50 years of its existence the Pharmaceutical Benefits Scheme (PBS) was free from significant public scrutiny or major controversy. More recently the PBS has come within the public gaze, with the dissolution of the Pharmaceutical Benefits Advisory Committee (PBAC) in 2001, controversial contested decisions regarding certain high profile drugs (e.g. sildenafil) and proposals to increase patient co-payments. With increased public scrutiny and debate (which is to be welcomed) it is useful to review briefly the operation of the PBS and consider ways in which it might be improved.

Pharmaceutical companies seeking to have a drug listed on the Schedule of Pharmaceutical Benefits are required to prepare a submission according to a comprehensive set of guidelines.[1] Since 1993 the guidelines have required the presentation of both economic and clinical data, so that comparative costs and benefits may be taken into consideration. Issues of cost are not considered until the clinical performance of a drug has been established so economic considerations are always placed within a clinical framework.

In this issue ...

The problems of providing medicines at an affordable cost, discussed by Ruth Lopert and David Henry, are not unique to Australia. Bernie O'Brien tells us that Ontario is dealing with similar dilemmas. Whether or not to subsidise a drug can be a difficult decision and Alan Evans (of Medicines Australia) says that the pharmaceutical industry would welcome more transparency in the process.

Even subsidised drugs attract co-payments so some patients attempt to save money by breaking their tablets. Roger Nation and Jennifer Marriott advise that dividing drugs can be dangerous.

Since glaucoma was last reviewed in *Australian Prescriber* many new drugs have been marketed in Australia. Ivan Goldberg compares these drugs with the traditional treatments for glaucoma.

As the Schedule is not a limited formulary, a drug such as an ACE inhibitor or non-steroidal anti-inflammatory drug, can be added even though several similar products are already listed. Generally, if a manufacturer is able to show that a drug is as effective as other listed drugs, and costs no more, it will be added to the list. Demonstrating equivalence of two therapies can be complex but once equivalence is satisfactorily established the comparison of costs is generally straightforward. The rule is that the average cost of treatment should not increase with the listing of the new drug. This is an example of cost-minimisation.

If a drug appears to have a therapeutic advantage (typically at a higher cost) over an appropriate comparator, the PBAC will attempt to determine the magnitude of that advantage and whether it is worth paying for. This is referred to as cost-effectiveness analysis. The interpretation of incremental cost-effectiveness is relatively straightforward where evidence of comparative efficacy is drawn from well-conducted head-to-head randomised controlled trials measuring major clinical end-points such as survival. It is more difficult when comparisons are based on surrogate end-points, when it may be necessary to ascribe a value to (for example) a reduction in blood pressure, or an improvement in spirometry.

Australia was the first country to introduce an explicit requirement for economic analysis as part of the process of selection of drugs for a publicly funded formulary. While other countries have since introduced similar requirements, the process is most highly developed and has been most closely reviewed in Australia. Through the application of economic evaluation and by virtue of the government's position as a monopsony purchaser, Australian drug prices are significantly lower than those in some overseas countries. On average, prices in the UK and Canada are 1.5 times greater and in the USA they are 2–3 times greater. By contrast, Australian prices are similar to those in France, Spain and New Zealand.[2] Despite this, PBS expenditure increased by more than 17% in 2001, to over $4 billion.[3] While the existing processes provide some control over prices they do not control prescription volumes or total costs.

The extent of use of a new drug depends on the epidemiology of the condition being treated, the degree to which patients seek treatment, and on uptake by prescribers. Numbers of

prescriptions depend, at least in part, on the intensity of promotion of the product. As economic evaluation is highly context-dependent, a drug that is cost-effective for a given indication and patient population may not be cost-effective if prescribed outside these settings. A useful example is ACE inhibitors. They are substantially more cost-effective in cardiac failure than in uncomplicated hypertension, where they offer no real advantage over beta blockers or thiazide diuretics and yet are significantly more expensive.[4]

In Australia, pharmaceutical companies spend large sums promoting their products. A drug may be promoted for any or all of the indications approved by the Therapeutic Goods Administration. PBS-listed indications are however often narrower. For example, advertisements for bisphosphonates used in osteoporosis are not required to mention that under the PBS the subsidy is confined to patients with a history of fracture following minimal trauma.

Leakage – the prescription of drugs outside PBAC-approved indications – is common. The overall cost of leakage is not known, but is likely to be high. When proton pump inhibitors were PBS-listed for severe grades of ulcerative oesophagitis a large proportion of PBS prescriptions were written for other indications.[5] This represents an 'opportunity cost'; in an environment where overall healthcare expenditure is capped, the funds to pay for leakage of PBS-listed drugs must be found from other programs. Ultimately, excessive use of expensive new drugs must reduce available funds for public hospitals and aged-care programs.

How can the situation be improved? There are a number of possible approaches to controlling the extent and costs of leakage. At a national level these include improving pharmaceutical company marketing and promotion, increasing the transparency of the decision-making process, and increasing the use of price-volume agreements or tiered pricing arrangements.

There is a strong case for requiring pharmaceutical promotion to provide information that is balanced to assist prescribers in choosing the best drugs for their patients. In the 2002–03 Budget, the government announced that it had reached agreement with pharmaceutical manufacturers to provide pertinent information to prescribers about medicines listed on the PBS.[6] In the course of their contact with doctors, medical representatives from drug companies are expected to inform them of the PBS prescribing requirements, and drug advertising material will henceforth include PBS prescribing information. It will be interesting to see how this works in practice.

There have been repeated calls for the PBS process to be made more transparent.[7] The operation of the PBAC is governed by the provisions of the National Health Act (1953), which require that the data submitted to the PBAC and the deliberations of the Committee remain confidential. Recently, the Department of Health and Ageing has published (on its web site) a quarterly summary of the PBAC's **positive** recommendations (including a brief summary of the basis on which each approval was made).[8] This is a welcome move, but the amount of information should be increased substantially, perhaps to the extent of including the comprehensive technical summaries prepared by the Economics Subcommittee of the PBAC. Currently, the identities of drugs that have been considered and rejected, and the grounds for rejection, remain confidential.

By contrast, in the UK this information is published by the National Institute for Clinical Excellence (NICE).[9] Consequently pharmaceutical companies, health professionals, consumer advocates, disease support organisations and the media have access to detailed information relating to the availability or non-availability of various healthcare interventions.

More extensive use could be made of price-volume agreements between the Government and manufacturers. Under these arrangements, the unit price of a drug is reduced when sales exceed a level that represents the limit of cost-effective use of the product. These agreements, which should be based on epidemiological and cost-effectiveness data, simulate market forces and share the cost of leakage between the manufacturer and taxpayers. An alternative would be to introduce a form of tiered pricing, in which the price paid to the supplier is based on the anticipated benefits of the drug when used in a range of indications or patient populations. Using the example of ACE inhibitors, this would mean that these drugs would attract a higher price when used in cardiac failure than they would in uncomplicated hypertension.

These suggestions are not a panacea and do not address the critical issue of prescriber behaviour. There appears to be a surprising readiness on the part of many prescribers to abandon well-established practices and enthusiastically embrace new drugs on the basis of promotional material, perhaps reflecting an insufficiently critical view of the superiority of new drugs. The recent tide of prescriptions for COX-2 inhibitors would suggest this is the case. Addressing the issue of prescriber behaviour is nevertheless fundamental because the future of the PBS and the welfare of patients who depend on access to affordable drugs lie in the hands of health professionals.

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