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Pharmaceutical benefits scheme cost recovery

Glenn P. Salkeld

University of Wollongong, gsalkeld@uow.edu.au

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Abstract

Since the beginning of 2010 the Australian Government has applied cost recovery to the listing process of the Pharmaceutical Benefits Scheme (PBS). Drug companies seeking to list their drugs on the PBS or vaccines on the National Immunisation Program pay a fee at two key points - upon lodgement of the application and at the pricing stage. The lodgement fee relates to the evaluation work of the Pharmaceutical Benefits Advisory Committee (PBAC) and all of its supporting administrative functions. The pricing fee relates to the pricing work of the Pharmaceutical Benefits Pricing Authority and its supporting functions. Companies that want an independent review of a PBAC recommendation to not list a drug on the PBS will also pay. The fees are not trivial - \$119 500 for a major PBAC evaluation, \$25 000 for a complex 'pricing' and \$119 500 for an independent review. Hardly spare change, even for a pharmaceutical company. So what is the purpose of the cost recovery scheme and what are the likely consequences?

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Pharmaceutical Benefits Scheme cost recovery

Glenn Salkeld, Head, School of Public Health, University of Sydney, New South Wales

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Since the beginning of 2010 the Australian Government has applied cost recovery to the listing process of the Pharmaceutical Benefits Scheme (PBS). Drug companies seeking to list their drugs on the PBS or vaccines on the National Immunisation Program pay a fee at two key points – upon lodgement of the application and at the pricing stage.¹ The lodgement fee relates to the evaluation work of the Pharmaceutical Benefits Advisory Committee (PBAC) and all of its supporting administrative functions. The pricing fee relates to the pricing work of the Pharmaceutical Benefits Pricing Authority and its supporting functions. Companies that want an independent review of a PBAC recommendation to not list a drug on the PBS will also pay. The fees are not trivial – \$119 500 for a major PBAC evaluation, \$25 000 for a complex 'pricing' and \$119 500 for an independent review.² Hardly spare change, even for a pharmaceutical company. So what is the purpose of the cost recovery scheme and what are the likely consequences?

In this issue...

The cost of the Pharmaceutical Benefits Scheme will always be a topic for debate, but it is important to know that the evaluations of cost-effectiveness are assessed by the independent Pharmaceutical Benefits Advisory Committee. Glenn Salkeld reassures us that the introduction of evaluation fees will not compromise this independence.

Independence is also important when assessing information about medicines. Rosalind Tindale tells us where to find independent sources of drug information.

Genetic information has changed the way haemochromatosis is investigated. Andrew St John, Katherine Stuart and Darrell Crawford review how to make the diagnosis.

The prognosis for patients with HIV has improved, but regular monitoring and adherence to treatment are essential. Tom Turnbull provides advice on how general practitioners can assist in management.

The management of sleep apnoea may also involve a range of health professionals. Stuart MacKay outlines some of the treatment options.

The stated purpose is to recover the cost of the services provided (evaluation and pricing) and to promote efficient allocation of resources.¹ Depending on your point of view it is either an attempt to gouge the pockets of industry or a 'fair cop gov'. After all, the pharmaceutical industry does very nicely from PBS price subsidies, and so does the Australian public. All parties benefit from the PBS – the key question is whether cost recovery threatens the very process that has delivered safe, timely and affordable access to prescribed medicines for all Australians.

Some of the early response to the cost recovery proposal has been reminiscent of the reaction when the PBAC started to assess the cost-effectiveness of drugs (National Health Amendment Bill 1987). It was feared that the extra cost of preparing submissions would result in Australia missing out on new drugs. However, the PBAC cost-effectiveness process is designed to reward sponsors with higher prices for drugs that provide greater clinical benefit than the drugs which are currently available. It does not reward those drugs that do not confer additional clinical benefit. Without the cost-effectiveness requirement the PBS would probably have sunk under the weight of its own success. It may still do so unless pharmaceutical expenditure is kept under tight control. There are, however, legitimate concerns about cost recovery.

The first concern is that PBS cost recovery may be the straw that will break the camel's back. The pharmaceutical industry is already carrying the load of lower profits, fewer blockbuster drugs in the pipeline and the high cost of getting a drug to market. Critics of cost recovery argue that some new drugs may never enter the Australian market due to higher costs of registration and PBS listing (or face lengthy delays in reaching our shores). Those that do will be more expensive (as companies will pass on the extra cost of PBS listing) and smaller companies may be driven out of the market. Furthermore, cost recovery may discourage development of drugs aimed at a lower volume market.

Let us get some perspective here. In 2008–09, the Australian Government spent more than \$7.679 billion on pharmaceutical benefits.³ That is taxpayer dollars that not only provide health benefits to millions of Australians but also contribute directly to bottom line industry profits. At face value industry can afford the extra impost of cost recovery. It is unlikely that new drugs

will be prevented or delayed in reaching the Australian market. The Australian pharmaceutical market is a competitive one and 'if a company decides not to launch a particular product in Australia, then competitors' products come in'.⁴ If there is no competitor then it is possible that a sole manufacturer may decide not to introduce a new product to the Australian market. It is a commercial decision. If cost recovery fees alone swing the manufacturer's net present value calculation of a new drug from a decision to submit (to the Therapeutic Goods Administration (TGA) and subsequently to PBAC) to 'not submit', then the case for registration and PBS listing is likely to have been marginal in the first place.

Another concern is that cost recovery may compromise the independence of the PBAC, because it will be paid by the drug companies. This fear appears to be unfounded because the PBAC has no direct pecuniary interest in the process. All the income from cost recovery fees goes into consolidated revenue rather than to the PBAC itself. Neither the Department of Health and Ageing nor the PBAC would actually see any of the 'cost recovery' funds. Historically the PBAC has shown itself to be strongly independent. Since 1998–99 the TGA has operated on a full cost recovery basis. I have not seen evidence to suggest that the TGA has been compromised by the introduction of cost recovery.

It is fair to say that a lot of effort has gone into making the PBAC process more transparent and responsive to the needs of drug companies and this preceded the introduction of cost recovery. The industry's expectations of the process may increase as a result of the new fees, with an understandable desire for quicker turnaround of PBAC submissions. Time will tell how the PBAC responds to the concurrent demands of meeting their legislative requirements and managing what is the inherently adversarial nature of negotiating drug prices.

Of course there are instances when the imposition of the cost recovery fee is not in the public interest. Under the National Health (Pharmaceuticals and Vaccines – Cost Recovery)

Regulations 2009² an exemption may be granted in respect of orphan drugs, the temporary supply of drugs or changes to an existing PBS listing. A fee waiver may be granted if 'the application involves the public interest and payment of the fee would make the application financially unviable'. This may apply when the patient population is not large enough to make the application financially viable, the product is to be used for palliative care or as a paediatric medicine, or for treatment of Aboriginal or Torres Strait Islander people.

For any change in policy it pays to be vigilant and monitor any unintended consequences. If experience is anything to go by, the PBAC process will survive. Numerous reviews and a few detractors have not weakened the inherent strength of a legislated process that supports evidence-based decision making.

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Professor Salkeld has received an honorarium from Pfizer for teaching a short course on 'cost-effectiveness of pharmaceuticals'.

Letters

The Editorial Executive Committee welcomes letters, which should be less than 250 words. Before a decision to publish is made, letters which refer to a published article may be sent to the author for a response. Any letter may be sent to an expert for comment. Letters are usually published together with their responses or comments in the same issue. The Editorial Executive Committee screens out discourteous, inaccurate or libellous statements and sub-edits letters before publication. The Committee's decision on publication is final.

Denosumab

Editor, – We welcome being recognised for transparency in supplying Therapeutic Goods Administration (TGA) evaluation data to *Australian Prescriber* to assist in the preparation of the new drug comment about denosumab (Prolia) (*Aust Prescr* 2010;33:194).

We were, however, surprised to read a statement, based on a meta-analysis¹ that 'denosumab was not associated with a significant reduction in fracture risk in postmenopausal women', despite your review having previously described a clinical trial which showed statistically significant reductions

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