



## Time for the Pharmaceutical Benefits Advisory Committee to set its own agenda

Drug subsidy recommendations should be informed by active assessment of current evidence and emerging treatments

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doi:10.5694/mja12.10152

Decisions about which medicines should be subsidised by the Australian Government on the Pharmaceutical Benefits Scheme (PBS) are based on recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC) — an independent statutory body appointed by the government.<sup>1</sup>

The PBAC lists among its goals maximising the “value” that Australia derives from its health expenditure and “meet[ing] the health needs of the majority of the Australian community”.<sup>2</sup> While the PBAC is generally thought to have in place good processes for working towards these goals, its decisions are increasingly contested by consumers, governments, clinicians and the pharmaceutical industry.<sup>3</sup>

For example, concern has been expressed about the PBS's subsidisation of ranibizumab (Lucentis), a vascular endothelial growth factor (VEGF) inhibitor used for the treatment of wet age-related macular degeneration (AMD), when a far cheaper and probably equally effective alternative — bevacizumab (Avastin), a VEGF inhibitor listed for cancer but not for AMD — was available.<sup>4</sup> The listing of ranibizumab, it was argued, was inconsistent with the goals of the PBAC and PBS because it is about 40 times more expensive than bevacizumab, and costs taxpayers over \$200 million each year (second only to atorvastatin and rosuvastatin).

A recent development has brought the issue to light once again: Bayer Healthcare and Regeneron Pharmaceuticals are, together, likely to seek PBS listing for yet another VEGF inhibitor, aflibercept (VEGF Trap-Eye), recently approved by the Therapeutic Goods Administration,<sup>5</sup> to

treat wet AMD. Although aflibercept has not been shown to have greater efficacy than ranibizumab, patients only need an injection every 2 months, compared with monthly for ranibizumab.<sup>6</sup> But even if this did provide some benefit to patients and reduced the cost of therapy, which it is only likely to do by a small degree, it would still leave bevacizumab unlisted, and taxpayers would still be paying significantly more than they need to, overall, to cover the cost of treatment for wet AMD.

One possible explanation for such a situation is that the PBAC currently relies entirely upon interested parties putting forward submissions for listing, rather than proactively seeking submissions in the public interest. In practice, this means that almost all submissions come from commercial sponsors, and the agenda of the PBAC is largely determined by the interests of the pharmaceutical industry. This is potentially problematic, because commercial sponsors are unlikely to go to the trouble of listing medicines for indications that are not commercially attractive.

In theory, there is nothing to stop professional societies or consumer organisations from making their own submissions to the PBAC in the public interest. However, non-commercial organisations seldom have the resources and expertise to conduct and synthesise the research into clinical effectiveness, cost-effectiveness and the broader impacts of health technologies that is needed to make a case for PBS listing.

But need this be the case? Some overseas agencies charged with health technology appraisal (eg, in the

United Kingdom<sup>7</sup> and Canada<sup>8</sup>) place more emphasis on setting their own priorities for health technology assessment than does the PBAC. We suggest that it may be possible to expand the role of the PBAC so that it has the power to, first, identify emerging or established pharmaceutical agents that might require evaluation on the basis of likely public interest ("horizon scanning"); second, invite professional societies to prepare submissions in these priority areas; and, third, provide the necessary financial and scientific support to these organisations so that they do not need to be burdened by prohibitive costs or legal liability.

Orphan drug provisions, which allow the PBAC to waive submission fees for medicines that have no sponsor or are not commercially viable,<sup>9</sup> go some way towards redressing the imbalance between commercial and non-commercial interests; but, even here, the onus is on professional and consumer organisations to initiate and prepare submissions.

In this regard, it is noteworthy that, in Australia, efforts have been made to initiate horizon scanning for non-pharmaceutical health technologies through the Australia and New Zealand Horizon Scanning Network (ANZHSN), which makes recommendations to the Medical Services Advisory Committee (MSAC).<sup>10</sup> Horizon scanning may:

- identify new technologies with major implications for the health system;
- control the adoption and use of technologies; and,
- identify underused technologies, as might be the case with the listing of bevacizumab for the treatment of AMD.<sup>10</sup>

Expanding the role of the PBAC would not be easy. It would probably require the establishment of a separate government-funded body that would conduct horizon scanning, make recommendations to the PBAC, seek submissions from relevant professional organisations and provide these organisations with the financial and administrative support that they would need to conduct or commission the necessary health technology assessments. A subcommittee of the PBAC, to whom the horizon-scanning body could make its recommendations, would probably also need to be formed.

And even if such a mechanism could be established, questions would remain, such as: Who should set priorities

for seeking PBS listings? What criteria should be used for prioritising potential listings (eg, novelty, financial impact, clinical impact, disease burden)? What processes should be used to identify areas of need (eg, specialty mapping, forecasting, public ranking exercises)? And how can such processes be inclusive and transparent?<sup>8,10</sup> Such practical difficulties are evident in the non-pharmaceutical medical technology sector in Australia, where, despite the existence of a separate government-funded horizon-scanning body, the impetus for the MSAC to conduct a health technology assessment almost always stems from an application by a commercial sponsor.<sup>10</sup> But, unless steps are taken in this direction regardless of such difficulties, the PBAC will be unable to reach its full potential as an agency committed to universal benefits and the systematic application of evidence-based decision making.<sup>11</sup>

**Competing interests:** No relevant disclosures.

**Provenance:** Commissioned; externally peer reviewed.

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