Wyeth Australia Pty Limited

Submission to the Productivity Commissioner

Impact of Advances in Medical Technology on Healthcare Expenditure in Australia
PROGRESS REPORT

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2 INTRODUCTION

Wyeth Australia Pty Limited welcomes the opportunity to comment on the Productivity Commission Progress Report on the Impacts of Medical Technology in Australia.

Wyeth is a research-based, global pharmaceutical company responsible for the discovery and development of some of today's most innovative medicines. It has a strong commitment to the local community and is committed to achieving the aim of the Australian Governments National Medicines Policy by delivering cost-effective medicines that allow optimal health outcomes within the framework of a viable pharmaceutical industry.

Wyeth has consistently demonstrated its leadership in therapeutic innovations that deliver breakthrough medicines requiring dedicated manufacturing plants associated with state of the art manufacturing processes.

A number of innovations, as developed by Wyeth, have been introduced to the Australian market. The most recent innovations are regarded as high cost medical technology. Despite the additional expenditure to the Pharmaceutical Benefits Scheme (PBS), the savings associated with treating a patient population that has an unmet clinical need is significant. The savings would be even more substantial if indirect costs and cost-offsets outside the healthcare sector (for example, productivity) were considered.

The comments prepared by Wyeth have focused on the application of the terms of reference to the case of innovative pharmaceuticals and where it is believed further refinement or clarification is required prior to the release of the Final Report.

Wyeth recommends its comments should be read in conjunction with the Medicines Australia submission to the Productivity Commissioner.

3 KEY DRIVERS FOR MEDICAL TECHNOLOGY DEMAND

The terms of reference (a) require the Productivity Commission to identify the key drivers of medical technology demand in Australia.

Recommendations

Timely access to individual affordable cost-effective medical technology needs to be a priority for the Australian Government as it avoids the use of less appropriate treatments and, thus, averts increased long-term expenditure.

The fundamental driver of medical technology demand in Australia is the desire to achieve and maintain a state of wellness through a universal access system that is able to deliver healthcare at a subsidised cost to individual patients.

3.1 Timely Access to Affordable Medical Technology

The National Medicines Policy has four central objectives to meet medication and related service needs so that both optimal health outcomes and economic objectives are achieved for all Australians. One of the central objectives is timely access to medicines that Australians need, at a cost individuals and the community can afford[1].

The ability of an individual to gain timely access to affordable medicines for the prevention, detection and management of acute and chronic disease states is a critical element of the Australian healthcare system. The existence of the PBS, delivering healthcare at a subsidised cost is a key driver of demand for medical technology.

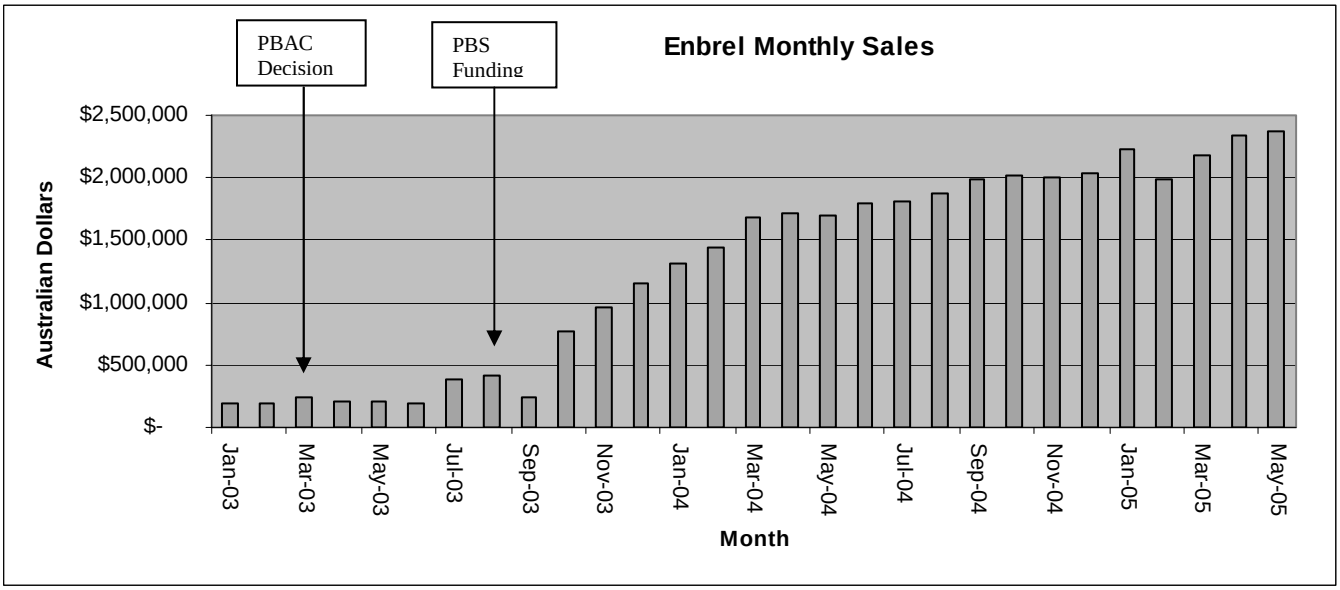
The strong relationship between timely access and affordability is clearly evident by the demand for medicines listed on the PBS. A leading example is the subsidy of Enbrel

[1] Commonwealth Department of Health and Ageing. *The National Medicines Policy*. Canberra: Publications Production Unit, Commonwealth Department of Health and Aged Care, 1999.

etanercept)[2] for a patient population with a high level of unmet clinical need and disability that had previously not had access to an effective, well-tolerated treatment. Despite the cost-effective medical technology being available, the prohibitive personal cost of Enbrel when first launched in the Australian market (September 2000) resulted in a slow up-take rate as compared to when Enbrel was first subsidised on the PBS by the Australian Government in August 2003.

The increased demand for Enbrel following PBS listing is presented in **Figure 1.** It is clearly illustrated that affordability (rather than the clinical need and benefit) was a key driver of patient uptake in the first 12 – 18 months of availability.

Figure 1: Enbrel Monthly Sales pre and post PBS listing



Source: Wyeth internal data: January 2003-August 2003, HIC Statistical reporting (http://www.hic.gov.au/providers/health_statistics/statistical_reporting/pbs.htm): September 2003 – May 2005

[2] Enbrel was the first biologic to be launched in the Australian market to treat rheumatoid arthritis. Rheumatoid arthritis is a disabling, progressive musculoskeletal disease, characterised by inflammation of the joints. Joints become painful, stiff, swollen and deformed in the long term, due to the ongoing inflammation. Symptoms are not restricted to joints and patients may experience fatigue, weight loss, anaemia, ulcers, skin problems, muscle weakness, inflammation of the heart, lungs, eyes, blood vessels and lymph glands. Rheumatoid arthritis is associated with a high level of morbidity and within 10 years of diagnosis, over 50% of patients with rheumatoid arthritis will have had to significantly reduce their work hours or cease employment completely (Access Economics, 2001).
Enbrel is currently TGA registered for the following indications: adult rheumatoid arthritis, juvenile chronic arthritis, psoriatic arthritis, ankylosing spondylitis and psoriasis (please refer to the full Product Information for complete details on the indications).

The Government is acutely aware of the increase in the uptake of medical technology following subsidisation of cost-effective medicines. A number of mechanisms have been introduced to ensure the medication is appropriately prescribed only to the patient population deemed to be cost-effective. Pharmaceuticals identified as being high cost, such as Enbrel, normally attract the most stringent measures.

Enbrel is subject to an authority-required approval process, where a clinician is required to complete an eight page form for evaluation by the Health Insurance Commission (HIC). The detailed form requires clinicians to include detailed information on a patient's treatment history and their disease pattern in order to demonstrate they are eligible for PBS supply. If they are not eligible, the patient must meet the total cost. The documentation is required for initiation, continuation (every 6-months a new continuation form is required to be completed) and change to an alternate biological that is PBS listed. An additional requirement is the clinician must complete the form in his/her own handwriting. This requirement is a significant barrier to the prescribing of Enbrel, especially in the era of electronic prescribing. Currently there is no mechanism in place to determine the number of patients who are denied access to this cost-effective therapy due to such prescribing barriers.

Recommendation:

Timely access to individual affordable cost-effective medical technology needs to be a priority for the Australian Government as it avoids the use of less appropriate treatments and, thus, averts increased long-term expenditure.

4 AGGREGATE IMPACT OF MEDICAL TECHNOLOGY ON HEALTHCARE EXPENDITURE

The terms of reference (b) require the Productivity Commission to identify the net impact of advances in medical technology on healthcare expenditure over the past ten years.

Recommendations

Determining the net impact of medical technology requires two core components, costs and benefits. Failure to appropriately consider all of the benefits of adopting medical technology will fundamentally distort the overall net impact and may lead to a misconception that growth in healthcare expenditure has not been delivered in a cost-effective manner.

Pharmaceuticals are recognised as one of the fastest growing categories of health expenditure. The cost-effectiveness framework used to ensure value for money of subsidized medicines is the most rigorous of applied efficiency tools within the entire healthcare sector. Therefore, pharmaceuticals may also be considered as one of the most significant areas to deliver cost-effective healthcare treatment. The value for money that is derived from the appropriate adoption of pharmaceutical treatment to society must be considered as opposed to the focused attention on increased expenditure for an isolated budget (the PBS Budget).

4.1 Aggregate Technology Expenditure Impacts

The net impact of medical technology on the healthcare expenditure over the past ten years needs to include two core components, costs and benefits. Failure to consider the benefits of adopting medical technology will fundamentally distort the overall net impact.

The Productivity Commission report clearly states there has been "no attempt to canvass the benefits provided by medical technologies"[3].

[3] Productivity Commission 2005, *Impacts of Medical Technology in Australia*, Progress Report, Melbourne, April (page 40 & 55).

It is accepted that medical technology has been a major driver of the growth in real healthcare expenditure over the past ten years and will more than likely continue to grow in future years. However, the increased growth in expenditure is not only attributable to the unit cost of medical technology being adopted, it also reflects the change (for example) in the Australian demographics and consumer expectations for medical treatment that provide greater benefit at zero risk. For example, recent clinical evidence demonstrates the clinical need for sirolimus in renal transplant recipients. It is believed that one of the main reasons that significant improvements in short-term graft survival have not translated into equally promising long-term benefits is the fact that cyclopsorin and tacrolimus are both associated with chronic nephrotoxicity (kidney-related toxicity) and hypertension. As sirolimus has a different mechanism of action, the nephrotoxicity and hypertension seen with current treatments (cyclosporin and tacrolimus) are avoided.

In addition, the increased growth in healthcare expenditure does not reflect the reductions in expenditure outside the healthcare system or the reduced indirect costs as a result of the medical technology being introduced. For example, Enbrel was introduced to treat a patient population with a high level of unmet clinical need and disability that had previously not had access to an effective, well-tolerated treatment. The introduction of Enbrel is expected to reduce the current estimated direct costs of treating rheumatoid arthritis of $700m and the indirect costs (such as lost productivity, early mortality) of $3.2 billion[4].

The difficulty in valuing the benefits of medical technology is acknowledged. Research on the benefits of technology advances in medical care, medical research and medical advances more generally are still in its infancy[5]. The most recent work suggests that the net benefits of high quality health care have produced gains in longevity in the United States that are very cost-effective. Lichtenberg (2005), using very conservative estimates, found that the value of the increase in ability to work attributable to new drugs is 2.5 times as great as expenditure on new drugs.

[4] Access Economics Pty Limited. March 2001. The prevalence, cost and disease burden of arthritis in Australia.

[5] Freund D & Smeeding T. The Future Costs of Health Care in Ageing Societies: Is the Class Half Full or Half Empty? Prepared for the Seminar: Ageing Societies: Responding to the Policy Challenges. Monday, 8 April 2002

Recommendation:

Determining the net impact of medical technology requires two core components, costs and benefits. Failure to appropriately consider all of the benefits of adopting medical technology will fundamentally distort the overall net impact and may lead to a misconception that growth in healthcare expenditure has not been delivered in a cost-effective manner.

4.2 PBS Technology Expenditure Impacts

Pharmaceuticals are one of the fastest growing areas of health expenditure in Australia. Accordingly, spending on medicines has become a target for cost-containment measures because of its continual growth, both in absolute terms and as a proportion of overall healthcare expenditure.

The PBS is designed to make available medicines that will have cost-saving effects on the use of other health-care and related resources (such as further GP visits, extended hospitalisation, productivity, etc). A cost-effective PBS, even when it is costing more in and of itself, will still be reducing expenditure in other areas[6].

Recommendation:

Pharmaceuticals are recognised as one of the fastest growing categories of health expenditure. The cost-effectiveness framework used to ensure value for money of

NOTE: The delay in reimbursement of Kineret was a result of the PBAC not accepting the clinical claim of equivalence (i.e. cost minimization) to TNF alfa antagonists.

Enbrel, as a leader in the therapeutic field, was ADEC recommended 15 months prior to an additional biological becoming available in the Australian market. However, there was only a 3-month difference in subsidised access to the medical treatment. Furthermore, the latest entrant into the biological market resulted in only seven months from recommendation of registration to reimbursement; this is significantly less than its main comparators.

The difference in the timeframe is fundamentally based on the cost-effectiveness framework within which the PBAC operates. Once a cost-effectiveness level was agreed, other bDAMRDs did not have to encounter the complexity of demonstrating cost-effectiveness, they simply demonstrated they were at least equal based on similar health outcomes and cost structure (i.e. demonstrated cost-minimisation). An exception was the listing of Kineret, which had to demonstrate cost-effectiveness after failure of a TNF alfa antagonist (Enbrel, Humira,or Remicade) rather than equivalence (i.e. cost minimisation) due to lower relative clinical efficacy.

An additional element of the delay is the perceived lack of affordability of high cost treatments by the Australian Government. As more and more high cost treatments are emerging, it is critical affordability issues are addressed prior to an independent third party recommending reimbursement on the basis of cost-effectiveness. Continued delay in reimbursement based on a perceived inability for the Government (or society) to afford the medical treatment is not the most efficient way to achieve a cost-effective healthcare system.

Recommendation:

Greater understanding of the costs and benefits of medical technology emerging in the Australian healthcare environment will allow a broader understanding of the value for money (cost-effectiveness) argument. The inclusion of key stakeholders will enable a broaden understanding and may lead to less barriers for the implementation and adoption of cost-effective medical technology.

6.2 Inclusion of Indirect Costs to determine the Cost-Effectiveness of Enbrel

Implicit in any discussion regarding health care is the assumption that declines in health status can and do impact on workforce participation and productivity. Most modern studies of disease burden or cost-of-illness include indirect (or productivity) costs.

Indirect costs refer to the cost of lost productivity as a result of premature death, inability to attend work (absenteeism) or reduced productivity on the job.

In general, changes in productive capacity as an outcome of therapy are not encouraged in submissions to the PBAC. The Guidelines state that while this may improve quality of life for the patient and could be included, quite legitimately, in a quality of life scale, it should not be assumed that there is an economic benefit to society through the patient's return to productive capacity. This outcome significantly reduces the ability of innovative medical technology to demonstrate an overall reduction in societal expenditure.

For example, rheumatoid arthritis is associated with a high level of morbidity and within 10 years of diagnosis, over 50% of patients with RA will have had to significantly reduce their work hours or ceased employment completely[9]. Enbrel is able to reduce the amount of productivity loss and therefore should be considered as part of the cost-effective argument.

In addition, one of the barriers to determining the net impact of advances in medical technology is the lack of appropriate health data, at both the aggregate and the individual level. For example, it is not possible to track resource use before and after the introduction of Enbrel. Currently, there is little incentive for sponsors to conduct post-marketing studies to assess the net impact of expenditure on specific technologies.

Recommendation:

Indirect costs and benefits to be included as part of a cost-effectiveness argument for the Government subsidisation of innovative medical technology.

[9] Access Economics Pty Limited. March 2001. The prevalence, cost and disease burden of arthritis in Australia.

Recommendation:

The linking of health data across different sectors of the Australian healthcare system, particularly longitudinal datasets, will facilitate assessment of the net impact of medical technologies.

6.3 Government Funding of Vaccines

The Australian Technical Advisory Group on Immunisation (ATAGI) was established in 1997 by the Commonwealth Minister for Health to advise and make recommendations on the technical and scientific elements of the National Immunisation Program. Since its development, ATAGI recommendations have informed the development and implementation of every technical change to the Australian Standard Vaccination Schedule (ASVS) and the National Immunisation Program.

From 1 January 2006, the funding advisory function of ATAGI will transfer to the PBAC in order to strengthen cost-effectiveness evaluations of vaccines, and streamline the process for considering vaccines funded under the National Immunisation Programme and the PBS. In addition, the vaccine price evaluation function will be transferred from the Department of Health and Ageing to the Pharmaceutical Benefits Pricing Authority.

The ASVS provides a list of all vaccinations recommended on the basis of disease burden, efficacy and cost-effectiveness on a population basis. The Australian Government funds most vaccines however some vaccines are not currently funded. The consumer must purchase any non-funded vaccine either through the doctor by prescription or through the local council immunization service.

The recommendation by ATAGI and later endorsed by the National Health and Medical Research Council (NHMRC) for the listing of vaccines on the ASVS previously resulted in automatic funding by the Federal Government[10].

However, it was unprecedented when the recommendations of ATAGI and NHMRC regarding Prevenar access for all children in September 2003[11] failed to result in automatic

[10] Commonwealth Budget 2005-2006. http://www.budget.gov.au/. Last accessed 28th May 2005.
[11] ATAGI made a positive recommendation in October 2002 and after public consultation, Prevenar was recommended in September 2003.

inclusion on the Commonwealth-funded National Immunisation Program. Although funding was initially provided for high-risk children, universal funding for the birth cohort was not instigated until January 2005. This delay in funding is largely due to a lack of any defined budget mechanism for purchasing of new vaccines. Unlike the funding of pharmaceuticals on the PBS, funding for vaccines must be secured as stand-alone items within the Commonwealth budget process.

Furthermore, in announcing the new funding advisory role of PBAC, the government also announced the abolition of the ASVS and intends to only publish funded vaccines via the National Immunisation Program. The ASVS has played a vital role by providing a list of important vaccines approved by ATAGI and NHMRC but not yet funded by the Commonwealth. Without this list, healthcare professionals and consumers will not be able to identify NHMRC-recommended vaccines that could be purchased privately.

Recommendation:
Create a funding mechanism that enables vaccines, which have been recommended by independent body as being cost-effective, to be available at an affordable cost to the Australian community. This funding mechanism should be an incorporation of vaccine purchasing within the PBS, or a similar stand-alone reimbursement system.

Recommendation:
Continue to publish the Australian Standard Vaccination Schedule as a complete list of vaccines recommended by the ATAGI/PBAC, regardless of Commonwealth funding arrangements.

6.4 Discount Rates for Vaccines

Discounting has the effect of reducing the cost-effectiveness of prevention programmes, where the costs are all borne ‘upfront’ and the benefits are achieved and maintained over many years. This causes many distortions to the cost-effectiveness estimates achieved in standard models.

The PBAC guidelines currently recommend that a 5% discount rate be applied to both costs and outcomes. Many of the pharmaceutical therapies evaluated by the PBAC require chronic treatment over many years before the desired outcome is achieved and, as such,

involve an ongoing investment that is extended over time. There is much controversy in the literature about the economic evaluation of vaccines, where the costs are all borne 'upfront' and the benefits are achieved and maintained over many years.

Beutels[12] published a review of economic evaluations of hepatitis B (1994-2000) and cited the inconsistencies of current evaluations. He called for the development of specific guidelines for economic evaluations of vaccines to improve the comparability between studies.

More generally, a technical paper by Smith & Gavelle[13] at the Centre for Health Economics, University of York examined recommendations for best practice on discounting for health effects as set out by government agencies, regulatory bodies, learned journals and leading health economics texts. The results demonstrate that nine of 16 expert sources recommend including a discount rate of less than 5% for health care costs (with some sources recommending that multiple discount rates be used). These nine sources include health authorities and expert groups from the USA, UK (including guidelines for the British Medical Journal), Canada, The Netherlands, France, and Belgium. In particular, the USA task force of experts (Gold, Siegel, Russell & Weinstein)[14], organised by the US Public Health Service, recommended that costs and benefits should be discounted at a 3% annual rate.

Recommendation:

Discounting has the effect of reducing the cost-effectiveness of prevention programmes, where the costs are all borne 'upfront' and the benefits are achieved and maintained over many years. Accordingly a separate discount rate should be applied (as the base case) for cost-effectiveness evaluations of vaccines, as unlike pharmaceuticals vaccines do not involve an ongoing investment that is extended over time.

[12] Beutels P. Economic evaluations of hepatitis B immunization: a global review of recent studies (1994-2000). *Health Economics*, 2001; 751-774.
[13] Smith D & Gravelle H. The Practice of Discounting Economic Evaluation of Health Care Interventions. Centre for Health Economics, the University of York. CHE Technical Paper Series 19, October 2000.
[14] Gold MR, Siegel JE, Russell LB, & Weinstein MC (1996). Cost-effectiveness in health and medicine. New York: Oxford University Press.

6.5 National Approach to Health Technology Assessment

Wyeth agrees with the preliminary finding 8.4 in the Progress Report:

> "*Australia's HTA effort is fragmented along jurisdictional (national and State/Territory) and sectoral (public and private) lines. This has led to duplication of HTA effort which can create unnecessary costs and delays.*
>
> - *There is potential for a nationally co-ordinated approach to assessing technologies used in public hospital systems*".

7 REFERENCES

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