
**Medicines Australia
Submission to the
Productivity Commission Progress Report**

***Impact of Advances in Medical Technology on
Healthcare Expenditure in Australia***

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INTRODUCTION

The pharmaceutical industry is committed to enhancing the health and quality of life of all Australians. Access to medicines into the future is vital for a healthy Australia. Medicines have played a pivotal role in improving the health of humanity.

Technological improvements in medicines have led to increased life expectancy, improved quality of life, increased productivity, enhanced workforce participation and is imperative to a more efficient health system. Medicines have eliminated diseases that in times past have been a major threat to human health.

Medicines Australia welcomes the opportunity provided by the Productivity Commission to make a follow up submission to its progress report on the Review: *The Impact of Advances in Medical Technology on Healthcare Expenditure in Australia*. Medicines Australia's initial submission focused on the application of the terms of reference to the case of innovative pharmaceuticals. This second submission provides information to the Commission on some additional issues of importance to consumers' future access to new medicines: horizon scanning and consumer involvement in health technology assessment.

"If ever we were punching above our weight around the world, it's in the area of medical science."

The Hon John Howard MP
Prime Minister of Australia
Garvan Institute, Sydney
16 May 2005

"For every \$1 that we invest in health and medical research there is \$5 economic spin-off."
Tony Abbott MP, AAP
6 July 2005

"Any savings need to be passed on to newer drugs which are being developed, ... to make sure that medicines remain affordable and accessible. The money we put into our PBS in fact may be a huge saving to our medical system because it prevents people from needing to go to hospital, allows them to stay in the community, allows them to live longer with a better quality of life."

Bill Glasson, AMA President, AAP
06 January 2005

"The pressure [on the PBS] will not go away because we are keeping more people healthy with pharmaceutical intervention. We are keeping more people out of hospital with pharmaceutical intervention. . . The economic truth is that restricting the availability of pharmaceuticals may generate even higher costs in other parts of the health system."

Dr Bill Glasson, AMA President, Speech to the 2005 AMA Parliamentary Breakfast
10 March 2005

HORIZON SCANNING

One means of potentially improving certainty for both the Federal Government and Industry in anticipating future growth in spending on medicines is the use of horizon scanning. Such activities, done in a collaborative exercise between the Government and Industry, can have a role in identifying new medical technologies in the pipeline and flagging how they might impact on the Industry, community and the Government.

The Commission noted in its progress report, that while Australia undertakes horizon scanning in the medical technologies of procedures and devices, it does not undertake such scanning for medicines¹. Other countries do undertake such scanning, such as Canada, Denmark, Switzerland, the UK and the US.

One of the Commission's findings (Preliminary Finding 7.1) identified that a current gap in the assessment of pharmaceuticals in Australia was the lack of horizon scanning in pharmaceuticals². The implication was that such activities should be undertaken in Australia.

The Federal Government already develops forecasts of the PBS in its Budget processes, unfortunately these are done without industry input and the assumptions underlying such forecasts are not available for Industry to verify their accuracy. Nor do current forecasts take into account future Industry trends. Ideally, such forecasts could be developed using extensive consultation with Industry.

The Federal Government confirmed during a recent hearing of the Senate Estimates³ that forward estimates for the PBS do not take into account the effects of either new medicines going off patent or new molecules in the pipeline which are anticipated for PBS listing. One of the reasons for this is that it is difficult to say what the impact of a particular molecule will be, whether a company will seek to list it in Australia or whether the PBAC would actually agree to list it (and what the time frame would be).

The recent Government sponsored review of post-PBAC arrangements⁴ identified the need to improve the exchange of information between the Federal Government and industry about likely market trends. The review found that the process needed to be more open to change and improve communication between Industry and the Government, particularly the Pharmaceutical Benefits Branch (PBB). The review recommended that:

¹ Productivity Commission 2005 *Impacts of Medical Technology in Australia: Progress Report*, April: Canberra, p. 134.

² *Ibid*, p. 168.

³ Senate Community Affairs Legislation Committee 2005 *Hansard: Budget Estimates*, 1 June 2005, p. CA77.

⁴ Department of Health and Ageing, Medicines Australia 2004 *Working together to improve the Pharmaceutical Benefits Scheme: review of post PBAC processes report*: Canberra.

Recommendation 13

PBB and Medicines Australia work towards a shared vision of future directions and sustainability by:

- a) PBB developing improved strategic capability in relation to PBS market analysis;*
- b) PBB and Medicines Australia sharing information around PBS market factors and trends;*
- c) PBB and Medicines Australia developing indicators to assess the effectiveness of pPBAC processes in achieving their objectives; and*
- d) PBB, Medicines Australia and PBPA meeting annually to discuss issues relating to the health of the system including strategic issues; procedural issues relating to the pricing and listing processes; and education programs.⁵*

Although the phrase 'horizon scanning' is not used in the recommendations, part of the ongoing dialogue recommended by the post-PBAC review includes sharing information around market factors and trends. This could include information about future technologies and their likely impact on the PBS.

While the process is underway to implement these recommendations, an important part of ensuring they achieve real change is encouraging policy to take on board the information coming out of the consultations and dialogue. For example, it is one thing to have a better understanding between companies and government officials on possible trends; it is another to have government policy and funding make provision for new technological developments and products likely to appear in Australia over the coming decade. Also important is ensuring that there is sufficient commitment and resources available to implement such a process.

The extent to which industry will be able to contribute to horizon scanning exercises will depend on the benefit such contributions would have and the Government's genuine commitment to their use. One reason why the Industry might want to get involved in horizon scanning would be to provide some level of certainty to Industry that when particular new technologies and products were ultimately submitted for listing the Government would have a greater understanding that these types of products were coming forward, and perhaps some provision in future budgets for such products. For Government, such a process would provide more certainty about the products coming forward in future years and the capacity to anticipate future demand and spending/investing in those medicines.

The benefit to Industry being involved is that if the Government is going to be undertaking some projections of new technologies and how they might impact on the PBS, it is in Industry's interest to ensure that the Government's assumptions are accurate, or at least based on credible information.

⁵ Ibid, p. 11.

It is for these reasons that the Industry in the United Kingdom works with the UK Government to forecast future spending on medicines. Ultimately the industry and Government derived benefit by exchanging data used in decision making about future spending on medicines.

Such exercises would need to take into account companies' commercial confidentiality requirements. A concern of Industry is to ensure that any such activities protect commercial-in-confidence material and companies are not required to reveal information they can demonstrate is commercially sensitive. How far Industry could go in providing information to the Government would need to be worked through. Ultimately the process would depend on the level of communication, interaction and commitment between the Government and Industry, and both parties accepting the benefits of undertaking such exercises.

Medicines Australia has, in the past, recommended that the Government and Industry could form an on-going Consultative Committee to encourage dialogue and information exchange on future products in the pipeline and likely impact on future Government expenditure.

The Consultative Committee could also provide a forum by which the Government receives information about the future medications that the pharmaceutical industry is producing and what timeframes are anticipated for these medicines being available to patients.

Government has in the past occasionally seen multiple medications become available for patients in a short period of time. This has in some cases resulted in unexpected movements in the total cost of the PBS and the accompanying concerns about the capacity to accurately forecast expenditure in this area.

Through dialogue, Government and Industry could identify what information would be of use to Government in forecasting accurately and how that information would best be collected. By delivering transparency and certainty to Government, greater confidence in the partnership between Industry and Government can be built with the end result being a better managed investment in new technologically advanced medicines.

CONSUMER INVOLVEMENT IN HEALTH TECHNOLOGY ASSESSMENT

The Productivity Commission Progress Report states that there is lack of consumer input into health technology assessment (HTA) consultation processes. The National Institute for Health and Clinical Excellence (NICE) in the United Kingdom provides an interesting case study of another model of consumer involvement in health technology assessment. NICE is the independent organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

NICE currently produces guidance in 3 areas:

- Technology appraisals - guidance on the use of new and existing medicines and treatments within the NHS in England and Wales;
- Clinical guidelines - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales; and
- Interventional procedures - guidance on whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use in England, Wales and Scotland.

Consumers can participate in the NICE technology assessment processes in several ways, as consultees (patient or carer groups) or as part of an organisation through the Patient and Public Involvement Unit and/or the Citizens Council.

Overview - Patient and Carer involvement

Opportunities for patient and carer involvement exist at a number of levels:

- National patient/carer organisations are consulted at all stages of guidance development;
- All NICE committees and working groups include at least two lay members with an interest in patient and carer issues;
- All NICE guidance is provided in formats written for patients, carers and the public; and
- From time to time, the Institute commissions additional work on patient and carer views to inform the development of its guidance.

NICE Technology Appraisal – The process

The appraisal process begins when a technology has been formally referred to NICE by the Secretary of State for Health and the Welsh Assembly Government.

First, NICE invites what it calls ‘consultee’ and ‘commentator’ organisations to take part. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents. Commentator organisations include manufacturers of the products with which the technology is being compared, NHS Quality Improvement Scotland and research groups working in the area.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval. The FAD is sent to consultees and commentators and is posted on the website. Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

NICE technology appraisal recommendations are prepared by an independent committee. The Appraisal Committee includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Not only do organisations representing patients and carers have a chance to be involved throughout the appraisal process as 'consultees', but professionals' and patient/carers' organisations can also nominate experts and patients to speak directly to the Appraisal Committee.

In summary, consultees can:

- Comment on scope of the appraisal;
- Submit evidence to the Appraisal Committee;
- Recommend other consultees whom they think should take part;
- Comment on the assessment report;
- Comment on the appraisal consultation document; and
- Appeal against the Appraisal Committee's final decision – the final appraisal determination.

To encourage further patient involvement in the development of guidance, NICE set up a Patient Involvement Unit.

Patient & Public Involvement Programme (PPIP)

On 1 April 2005, NICE took on the functions of the previous Health Development Agency, responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health. As a result of these changes, the Patient Involvement Unit (PIU) is now known as the Patient & Public Involvement Programme (PPIP).

The Patient and Public Involvement Programme (PPIP) provides advice on patient and carer involvement and identifies patient and carer organisations

interested in contributing to its work programme. The PPIP promotes effective patient and carer input by providing training and support to patient and carer organisations, and to those patients, carers and lay people who contribute to the NICE work programme.

PPIP supports the development of technology appraisals

The PPIP works with NICE to:

- Develop and support effective patient and carer input to its technology appraisals programme;
- Promote the effectiveness of patient and carer input by providing information, training and support to individual patients and carers and patient and carer organisations;
- Support patient and carer organisations who wish to make written submissions of evidence to individual NICE technology appraisals; and
- Support individual lay people who make verbal submissions to the Technology Appraisal Committees.

PPIP supports the Institute's Independent Advisory Committees

The Institute's independent advisory committees include healthcare professionals working in the NHS and people who are familiar with the issues affecting patients and carers.

The PPIP works with NICE to:

- Identify and recruit lay people onto its advisory committees; and
- Support lay input by providing information, training and support to lay people on the committee.

PPIP supports the development of Clinical Guidelines & Cancer Service Guidance

Clinical guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales. Service guidance aims to provide advice on how services in the NHS should be organised to provide effective services to people with certain conditions.

The PPIP works with NICE to:

- Advise the NICE guidelines team on patient and carer issues;
- Identify appropriate patient and carer organisations to register, if they wish, as stakeholders for individual guidelines;
- Seek out nominations from patients and carers to join Guideline and Guidance Development Groups (the groups that produce clinical guidelines and service guidance on behalf of the Institute);
- Support the guideline developers (the National Collaborating Centres) and patient and carer members of guideline groups on involvement issues throughout the development process;
- Advise on methods for involving patients and carers in the work of the Collaborating Centres and their Guideline Development Groups;
- Provide formal training and informal support to the Collaborating Centres and to patient and carer members;
- Comment, from a patient and carer perspective, on all draft documents; and
- Review, from a patient and carer perspective, the NICE guideline process.

Citizens Council

The Institute set up a Citizens Council, with 30 members drawn from all sections of the population, to have their say on wider issues. The Citizens Council helps NICE find out what members of the public think about key issues informing the development of the guidance NICE issues. Council members reflect a cross section of age groups, social circumstances, ethnic backgrounds, regional differences and abilities. Their views and opinions provide a backdrop against which NICE and the independent Committees that advise it can develop their recommendations.

The Citizen's Council brings the views of the public to NICE decision-making. The Council meets twice a year in 3-day sessions, and members deliberate on questions put to them by the Board of NICE. Meetings are open to the public.

Choosing members of the Citizens Council

The last time Council members were recruited it was carried out at arm's length from NICE by independent facilitators. Council members were chosen from around 4,400 individuals who responded to widespread publicity. Because groups such as NHS employees, suppliers to the NHS, and patient groups already have a strong voice in making their opinions known in the decisions NICE makes, applications from anyone in these groups were declined.

Citizens Council meetings

The Council meets twice a year in public and each meeting lasts up to three days. Councillors are paid £150 per day when on Council business, and their travelling and accommodation expenses are covered. NICE decides on the topic it wants the council to discuss. The independent facilitator organises the meetings and produces reports summarising the Council's views that are sent to NICE. The meetings are deliberative in nature and draw on a range of expert witnesses who give evidence on the issues under consideration. Council members help to choose these witnesses and are able to ask them questions. Case studies and role play help Council members to debate the issues raised and voice their opinions.

Citizens Council issues discussed

In the past, the Council had been asked by the NICE Board to consider and report on issues such as clinical need, whether there are circumstances in which age should be taken into account when making decisions and whether the NHS should pay for medicines to treat very rare diseases.

Use of Citizens Council's advice

NICE uses reports from the Council in two ways. First, NICE is developing a document on the scientific and social value judgements that will inform the work of the independent groups and experts who develop NICE guidance for the NHS. Second, NICE has been reviewing the methodology used to develop its guidance and the work of the Council has informed these reviews.

Suggested topics for NICE Guidance

Several different groups suggest topics on which NICE should develop guidance:

- Health professionals, patients, carers and the general public suggest topics on which they think a NICE public health intervention or programme, technology appraisal or clinical guideline would be useful;
- Clinicians suggest topics for interventional procedures guidance;
- The National Horizon Scanning Centre suggests emerging health technologies that might need to be assessed by NICE; and
- The Department of Health's National Clinical Directors and policy teams suggest topics.

Anyone can suggest a topic for a public health intervention or programme, technology appraisal, interventional procedure or a clinical guideline on the NICE website (www.nice.org.uk). The Department of Health also decides whether they wish to refer the topics to NICE.

The New Merged NICE

The new National Institute for Health and Clinical Excellence (NICE) has taken on the functions of the Health Development Agency to create a single excellence-in-practice organisation responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health.

The National Institute for Health and Clinical Excellence will produce guidance in three areas of health:

- Public health - guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector;
- Health technologies - guidance on the use of new and existing medicines, treatments and procedures within the NHS; and
- Clinical practice - guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.

The guidance will be produced by three 'centres' within NICE: the Centre for Public Health Excellence, the Centre for Health Technology Evaluation, and the Centre for Clinical Practice. NICE is currently consulting on the aims and functions of the Centre for Public Health Excellence and the processes it will use for developing guidance in public health.

Currently NICE produces two kinds of guidance on the promotion of good health and the prevention of ill-health:

- Public health intervention guidance – recommendations on locally delivered activities to reduce people's risk of illness or to promote healthy lifestyles; and
- Public health program guidance – recommended strategies, policies and multi-level action to improve health and reduce inequalities.

NICE public health guidance is for those working in the NHS, local authorities and the wider public, private and voluntary sectors.