Australian Government
Department of Health and Ageing

MEDICINES Australia
BETTER HEALTH THROUGH RESEARCH AND INNOVATION

2008 Joint Medicines Policy Conference

Outcomes

25 – 26 November 2008

Canberra

Background

The Second Joint Policy Conference was held in 2008 and built on the first ever Joint Policy Conference which was held in 2006. Medicines Australia and the Department of Health and Ageing have now collaborated twice to bring a range of stakeholders together to discuss issues of joint interest in the Pharmaceutical Benefits Scheme. These conferences are pivotal in facilitating discussion on the varying perspectives on how public subsidy of medicines best operates in Australia, with a particular emphasis on the assessment of medicines through the Pharmaceutical Benefits Advisory Committee (PBAC).

The 2008 Conference

The second Joint Policy Conference was held on 25-26 November 2008 in Canberra. The conference attracted over 350 delegates, a 20% increase over the 2006 conference. Conference attendees included representatives from the various industry sectors, government departments, PBAC, consumer groups, pharmacists, medical practitioners, medical researchers, the media and international visitors.

Key Speakers

- The Honourable Nicola Roxon MP, Minister for Health and Ageing, Australia.
- Professor Sir Michael Rawlins, chair of the National Institute of Health and Clinical Excellence (NICE), United Kingdom.
- Dr Durhane Wong-Rieger, PhD, founder and head of the Consumer Advocare Network, Canada.
- Emeritus Professor Lloyd Sansom, chair of the Pharmaceutical Benefits Advisory Committee, Australia.

Conference Outcomes

In the closing session of the Conference, Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, Mr Will Delaat, Chair of Medicines Australia and Lloyd Samson, Chair of the Pharmaceutical Benefits Advisory Committee (PBAC), addressed the Conference on the nine (9) key outcomes.

Medicines Australia and the Department of Health and Ageing agreed to undertake further dialogue and collaborative work on these outcomes through the Access to Medicines Working Group (AMWG) and other consultative forums. This would include consultation with other stakeholders as appropriate.

Through the invitation of Medicines Australia a significant number of consumers and consumer representatives were able to participate in this second conference. Their contribution was particularly valuable and Medicines Australia and the Department agreed that any future conferences would seek an even greater involvement for consumer groups through engagement in conference planning.

Outcome 1: Improved Speed of Access to New Medicines

The National Medicines Policy encourages collaboration between industry and Government to improve positive health outcomes for all Australians through their access to and wise use of medicines. A key objective of the conference was to examine ways in which Australians can continue to have timely access to newly subsidised medicines.

AMWG will monitor projects that aim to improve the speed of access to quality new medicines by the Australian public. The projects may take into consideration:

- **TGA Processes:**

Medicines Australia and the Therapeutic Goods Administration will work together to gain efficiencies in the registration process.

- **TGA/PBAC Overlap:**

AMWG will continue to work on the overlap and possible streamlining of TGA and PBAC processes.

- **Post PBAC Processes:**

AMWG will continue to work to expedite, where possible and appropriate, the process of listing medicines on the PBS after a positive PBAC recommendation.

It was agreed that any improvements to efficiency could not be at the expense of continuing to assure the safety, clinical effectiveness and cost-effectiveness of new medicines, and new ways of subsidising medicines.

Outcome 2: Integration of Health Technology Assessment (HTA) Within and Beyond Medicines

The development of targeted therapies presents challenges to the way in which the various aspects of an integrated care model are managed and delivered. A number of advisory committees make recommendations and give advice to the Minister of Health and Ageing on Health Technologies in Australia. The Conference focussed on two key committees involved in assessing medicines and medical devices for subsidy in Australia:

> The Pharmaceutical Benefits Advisory Committee (PBAC) considers the effectiveness and cost of medicines and vaccines for which subsidy is requested and makes recommendations and gives advice to the Minister about which medicines should be subsidised through the PBS and which vaccines should be funded through the national Immunisation Program (NIP).
>
> The Medical Services Advisory Committee (MSAC) advises the Minister on evidence relating to the safety, effectiveness and cost-effectiveness of procedures and other medical technologies. This advice informs Australian Government decisions about public funding through the Medicare Benefits Scheme (MBS) for new, and in some cases existing, medical procedures including diagnostic tests associated with targeted therapies.

On occasion, PBAC recommends medicines for PBS subsidy that require patients to undertake certain medical tests as part of a treatment involving subsidised medicines. If the required test has not been evaluated by MSAC for cost effectiveness, access to the therapy could be hindered.

The Department and the PBAC will work with MSAC to strengthen linkages between these two advisory bodies to deliver improved efficiency in the delivery of integrated care.

Outcome 3: Ongoing Review of Appropriateness of Evidence

Development in Health Technologies has resulted in the need to question if the evidence required in the past, to assess cost-effectiveness, quality and safety, is still relevant today. In order to assess new technologies, new forms of evidence may be necessary to address issues that are relevant to today's needs.
The Department, PBAC and Medicines Australia will consider ways in which health technology developers can be encouraged to collect and submit evidence that will better equip the PBAC in making its decisions; this may include evidence related to:

- quality of life
- social values
- future developments impacting or being affected by decisions made today (horizon scanning).

The Department, PBAC and Medicines Australia will continue to develop this outcome.

Outcome 4: Opportunities to improve consumer input and engagement

The conference identified the need for more robust consultation with patients and carers when making decisions on Health Technologies that affect 'their' condition and way of life. Consumer representatives expressed the importance of decision makers being given the opportunity to hear of the impact of living with a condition that will be treated by a medicine under consideration.
The Department will work with consumer organisations to develop improved strategies to encourage informed input to key decision contexts, with special regard to decisions about:

- individual medicines;
- medicines policy; and
- the way that Health Technologies are assessed.

The Department and Medicines Australia committed to ensuring consumer representation on the organising committee of the next joint policy conference and other joint activities.

Outcome 5: Improve Industry Participation

The conference identified that the Australian System of assessing medicines for subsidisation does not always harness the extensive experience that the pharmaceutical industry has developed from the international environment.

The Access to Medicines Working Group is an example of the constructive outcomes that can be drawn from collaborative efforts between the Department and Medicines Australia. Further measures involving other industry bodies will be explored to ensure that the international experience of companies is captured leading to improved policy development and a better system for funding medicines in Australia.

Outcome 6: Data

The conference discussed issues around post market data and the impact of this on medicine subsidy in Australia when it is not effectively captured, restraining the ability to analyse the needs of the Australian community. The conference examined a number of options to address improved data collection including:

- Medicines Australia and the Department working with other relevant entities such as the National E-Health Transition Authority and Medicare Australia to facilitate improved collection of PBS, MBS and hospital data;
- Further collection of relevant data for special patient groups (see Outcome 9); and
- The Department working with Medicare Australia and the Pharmacy Guild of Australia to better capture all medicines processed under PBS arrangements (specifically to capture the use of below co-payment medicines to the same level of detail as the use of above co-payment medicines).

AMWG will also consider the appropriateness of Coverage with Evidence Development (CED). This term was coined by the Centers (sic) for Medicaid and Medicare Services (CMS) to define instances where new technologies were funded ("covered") conditional upon the collection of improved evidence to confirm that the decision to cover the technology was the correct one.

Outcome 7: Promote Ethos of Quality Use of Medicines

Misuse, overuse and under use of prescription medicines (accidental and deliberate) was acknowledged as a major problem facing the health industry in Australia, often leading to increased hospitalisations and mortality.

The Conference identified that there is a need to engage more fully the pharmaceutical industry, governments, consumers, health professionals and other relevant QUM partners such as the National Prescribing Service to ensure a collective, co-ordinated strategy is developed to ensure the quality use of medicines by the Australian population.

This is best achieved through the leadership of the new National Medicines Policy committee structure. The role of each stakeholder will be established prior to expanding the current strategies associated with Quality Use of Medicines.

Medicines Australia and the National Prescribing Service will work together and establish more formal linkages on industry role in QUM.

Medicines Australia and PBAC/TGA will examine ways in which they can work together on how QUM can be integrated into the continuum of a drug life cycle from development though to the end user.

Further information on QUM is available at:
http://www.health.gov.au/internet/main/Publishing.nsf/Content/nmp-quality.htm

Outcome 8: Funding Arrangements

As there continues to be uncertainty in the evidence available when PBS-listing of new medicines is being sought leading to ongoing difficulties in appraising the health outcomes and cost-effectiveness of these medicines, it is important to develop strategies that reduce or manage identified sources of major uncertainty.

AMWG will continue to explore options aimed at reducing or better managing uncertainty in submissions to the PBAC. As noted above, there are particular uncertainties in the area of targeted therapies because of the co-dependence on supporting evidence for the other technology.

Outcome 9: Ensuring Appropriate Access for Special Patient Groups to Pharmaceuticals

Anecdotal evidence suggests that special patient groups in the Australian population may not have sufficient access to the medicines required to meet their specific need. The Department has set up a number of working groups which examine the needs of these groups and suggest specific medicines for inclusion on the PBS for their benefit. These working groups include:

- Expert Advisory Panel for Aboriginal and Torres Strait Island People
- Paediatric Medicines Advisory Group
- Palliative Care Medicines Working Group.

Evidence supporting the needs and interests of these special patient groups is required to ensure the pharmaceutical industry and government are pro-active in developing and subsidising suitable medicines. There is also a need to consider the consequences of the fact that there is rarely high quality evidence which directly informs the effectiveness and cost-effectiveness of medicines in these groups.

The Department, Medicines Australia and pharmaceutical companies which supply relevant medicines will continue to monitor and support the working groups in obtaining data and evidence to help ensure that special patient groups have access to the medicines they require.

Administration

Conference Organising Committee

Lloyd Sansom (Pharmaceutical Benefits Advisory Committee)
Brendan Shaw (Medicines Australia)
Diana Macdonell (Department of Health and Ageing)
Michael Fitzsimons (Medicines Australia)
Andrew Mitchell (Department of Health and Ageing)
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Paul Storey (Department of Health and Ageing)
Romina Bommes (Medicines Australia)
David Grainger (Eli Lilly)
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Conference Facilitator

Laurie Wilson, Stone Wilson Consulting

Conference Organiser

Conference Solutions

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