



Outcomes of the 2008 Conference and Work of the Access to Medicines Working Group

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Outcome 1: Improved Speed of Access to New Medicines

Progress to date

- ✓ Parallel processing of TGA and PBAC applications implemented – 1 January 2011
- ✓ Streamlining TGA processes
- ✓ Managed Entry Scheme – 1 January 2011
- ✓ MOU - 6 month consideration of Cabinet referred medicines



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


Progress to date

- ✓ 2009 HTA Review
- ✓ Co-dependent technologies
 - Alignment of MSAC and PBAC processes
 - Health Technology Assessment Access Point (HTAAP)



Outcome 3: Ongoing Review of Appropriateness of Evidence

Progress to date

- ✓ Ongoing PBAC investigations - appropriate level of evidence
 - July 2010 PBAC forum on factors influencing decision making
 - ✓ PBAC Guidelines Working Group
 - ✓ Managed Entry Scheme
 - Beyond RCT level evidence (Phase 2)
 - ✓ Pre-conference technical symposium – JMPC 2011
 - Confounders in data sets – 29 Aug
 - ✓ Session 3 JMPC 2011 - Day 1
 - Defining data linkages
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Outcome 4: Opportunities to improve consumer input and engagement

Progress to date

- ✓ Publication of PBAC agenda
- ✓ Consumer inputs to PBAC decision making process
 - Consumer Reports to PBAC
- ✓ PBAC public summary document
- ✓ Consumer involvement in planning and shaping of JMPC 2011
- ✓ Pre-Conference Consumer Workshop – 29 Aug 2011



Outcome 5: Improve Industry Participation

Progress to date

- ✓ Similar Biological Medicinal Products Working Group
 - MA, GMiA, AusBiotech, TGA and DoHA
- ✓ HTA influence on drug development
 - Workshop 2010/2011
 - Session 7 – JMPC 2011
- ✓ Joint Monitoring of trends in and drivers of PBS
- ✓ Horizon Scanning
- ✓ Pharmaceutical Industry Discussion Group



Outcome 6: Data

Progress to date

- ✓ Collection of 'below the General co-payment' PBS data
 - commences April 2012 as part of the Fifth Community Pharmacy Agreement
- ✓ Post Market Monitoring - Budget 2011-12
 - National Prescribing Services along with Drug Utilisation Sub-Committee (DUSC)
- ✓ Managed Entry Scheme



Outcome 7: Promote Ethos of Quality Use of Medicines

Progress to date

- ✓ National Medicines Policy Committee
- ✓ NPS - *be Medicines wise* Campaign
- ✓ National Medicines Symposium – every two years
- ✓ Post Market Monitoring – NPS and DUSC



Outcome 8: Funding Arrangements

Progress to date

- ✓ Managed Entry Scheme
 - Phase 1: RCT level evidence & other 'fit for purpose' evidence
 - Phase 2: Beyond RCT level evidence e.g. observational data
- ✓ Co-dependent technologies
 - Improving MSAC processes and transparency



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

Progress to date

- ✓ Paediatric Medicines Advisory Group
 - Priority list of medicines
 - New medicines listed on the PBS
- ✓ Expert Advisory Group
 - Focus on medical needs of Indigenous Australians
- ✓ Life Saving Drugs Review 2009



Future work for AMWG

- **Monitoring the implementation of MOU**
 - Parallel processing
 - Managed Entry Scheme (MES)
 - Ground work for Phase 2 of MES with PBAC and DoHA – observational datasets



Future work for AMWG

- **Monitoring the implementation of MOU**
 - Evidence to support policy development
 - Horizon scanning and tracking of PBS expenditure drivers.
 - Effect of reduction in F2 prices on the entry of new medicines.
 - Report to the Minister for Health and Ageing on the progress and implementation of the Memorandum of Understanding (MOU) – by 31 December 2011



Future work for AMWG

- **Co-dependent technologies**
 - manage transition arrangements and implementation issues.
 - development and implementation of Health Technology Assessment Access Point (HTAAP) functions.
- **Post Market Monitoring**
 - Industry keen to participate
 - Potential synergies with Managed Entry Scheme



Future work for AMWG

- **Influence of HTA in shaping future drug development**
 - Workshops (ongoing) to further develop understanding of how HTA processes provide investment signals
 - JMPC 2011 - Session 7 (Day two).
- **Transparency**
 - Further work on putting drug utilisation data into the public domain (Predicted vs. Actual)





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