Access to Medicines Working Group
Meeting 13
Minutes

3:30pm to 5:30pm, Thursday 25 August 2011
Medicines Australia, Deakin ACT

The AMWG agreed on the recommended action relating to each of the agenda items.
These minutes record discussions under agenda items and may not reflect the actual order of discussion.

Item 1 – Welcome and apologies
Mr Delaat welcomed the attendees on behalf of the AMWG co-chairs.

Department of Health and Ageing

- Mr David Learmonth
  Deputy Secretary
  Department of Health & Ageing
- Ms Felicity McNeill
  Acting First Assistant Secretary
  Pharmaceutical Benefits Division
- Ms Adriana Platona
  Assistant Secretary
  Pharmaceutical Evaluation Branch
- Mr Nick Henderson
  Assistant Secretary (Acting)
  Policy Analysis Branch

Medicines Australia

- Mr Will Delaat
  AMWG Co-Chair
  Chair, Medicines Australia
- Dr Brendan Shaw
  Chief Executive
  Medicines Australia
- Mr Andrew Bruce
  Director, Health Policy and Research
  Medicines Australia
- Mr David Grainger
  Global Public Policy Director
  Eli Lilly and Company
- Mr Mendel Grobler
  Director, Patient Access
  Pfizer Australia

Non-AMWG participants

- Mr Andrew Mitchell
  Strategic Advisor
  Pharmaceutical Evaluation Branch, DoHA
- Dr Brian Richards
  Director, Quality Use of Medicines & Industry Information Section, DoHA
- Ms Julie Cutts
  Director
  Health Technology Taskforce, DOHA
- Mr Amish Chaturvedi
  Research Manager
  Medicines Australia

Secretariat (DoHA)

- Mr Fred Connellan
  Acting Director, Budget Policy and Sustainability Section, DoHA
- Mr Christian Andersen
  Officer, Budget Policy and Sustainability Section, DoHA

Apologies
The meeting noted Ian Noble (Amgen) as an apology.

Item 2.1 – Minutes from 19 May 2011 AMWG Meeting
The AMWG agreed to incorporate Medicines Australia's suggested changes to the draft minutes.

M13 A1 – AMWG Secretariat to amend 19 May 2011 meeting Minutes as agreed and finalise.

Item 2.2 Action Items from 19 May 2011 AMWG Meeting
The AMWG noted progress against the action items of the 19 May 2011 meeting.

The meeting noted the revised date for the PBAC-Medicines Australia meeting likely to occur 26 or 27 November 2011. The reason for changing the dates was that the original date of 19 September 2011 was too close to the arrival of the new PBAC chair. The meeting noted that outgoing PBAC chair Professor Lloyd Sansom would be working for the Department of Health and Ageing (the Department) in the future.

Item 3 – MoU Implementation
The meeting agreed that the MoU implementation table would be handled by exception.

Item 3.1 – Managed Entry Scheme
Ms Platona provided an update on the Managed Entry Scheme (MES), noting that no applications had been received under the MES to date. Although it was initially thought one company would be making an application, closer talks between Medicines Australia and the company discerned that the potential application would not fall under the MES. The meeting heard that companies may be nervous about making an application under the scheme and were waiting for others to be the first movers.

Mr Delaat indicated that stage one of the MES was underway and that there was interest in what other forms of evidence may be appropriate in the second phase of the MES.

Item 3.2 – Parallel processing of TGA and PBAC applications
Ms Platona provided an update on the parallel processing of the Pharmaceutical Benefits Advisory Committee (PBAC) and Therapeutic Goods Administration (TGA) applications. Out of 12 applications originally received for the July PBAC meeting, seven had received the Delegate Overview and were considered with four being approved. The meeting heard that these four approved applications would not otherwise have been considered if not for parallel processing. Of the three applications not approved, two were rejected and one was withdrawn. Of the other five applications, four were rejected (mostly on cost-effectiveness grounds) and one was withdrawn.

The meeting heard that the Department is considering issues around how to communicate outcomes for drugs on the PBAC agenda without a Delegate Overview, and will be seeking Medicine Australia's assistance in this work.

Mr Delaat asked for the Department and the PBAC's view of these new arrangements. The meeting heard that there was now more work for the PBAC to consider and it depended on companies providing the right information at the right time.

In addition, the meeting heard that there was international interest in the parallel processing changes underway in Australia.

Item 3.3 – Joint Monitoring of PBS expenditure

Mr Henderson noted the first report on joint monitoring was now with the AMWG for endorsement, thanking Mr Connellan and Mr Chaturvedi for their work on the report. The meeting heard that the Data Working Group had made good progress in this resource intensive exercise. The first report focuses on a subset of expenditure drivers with the second report looking at the remaining agreed set of drivers. The importance of feedback on the report was noted as it was the first one tabled with the AMWG.

Mr Delaat stated that the report was a fantastic piece of work and thanked those involved. He noted that this was the first iteration of the process and that references to the relevant time periods used in the analysis could be more explicit given that different graphs had different timeframes. It was suggested a preamble to the document could address this. Mr Learmonth noted that the drivers contributions to expenditure seemed clear, but that their contribution to growth was not as clear.

The meeting discussed the potential to draw conclusions from the data and to provide interpretations. It was noted that it would be more useful to draw conclusions on the contributions of the main contributors to growth once the full range of drivers had been considered. Doing so at this point in time could be premature. After investigating the full range of drivers, the proper context would allow for more robust conclusions. It was also noted that while conclusions should be offered to provide context for the individual drivers, the report does not need to draw policy conclusions regarding the sustainability of the Pharmaceutical Benefits Scheme (PBS).

The meeting heard discussion about the benefit of making the report publicly available upon completion with Mr Learmonth noting that this was a matter for the Minister for Health and Ageing to decide. The meeting noted that the AMWG is to agree the communications strategy for the report. The meeting heard that the report had the potential to be published in an academic publication such as the Medical Journal of Australia.

The meeting heard that the next part of the report containing analysis of the second set of drivers would be ready for presentation at the December AMWG meeting. The meeting agreed to hold a further Data Working Group once Medicines Australia and the Department had collected respective comments on the draft.

The meeting noted that the joint monitoring report could be presented to other stakeholders through the Pharmaceutical Industry Working Group.

M13 A2 – The Data Working Group to develop a communications strategy for the Joint Monitoring report.

M13 A3 – The Department to approach the Minister for Health and Ageing regarding the timing and content of a public release of the Joint Monitoring report.

M13 A4 – The Data Working Group to present the second Joint Monitoring report at the December 2011 AMWG meeting. The second report is to incorporate the first report and comments from the AMWG on the first report.

Item 3.4 – Horizon Scanning
Mr Bruce provided the meeting with an update of horizon scanning issues, noting that the AMWG has agreed to a broader methodology. The paper presented incorporates a Beta-scan, giving an example of what this methodology would look like. Feedback on its application was welcomed as well as advice on how this could feed into policy.

Mr Crompton noted that Medicines Australia now have a database for the first collection of data, with the methodology used for this contained in the paper presented. It should be reproducible to a broad extent. An outstanding question relates to the appropriate type of filtering. Mr Henderson noted that the medium-term scan was useful as a case study.

Mr Delaat said that it would be interesting to get an idea of what the Department and the PBAC will be using the information for. Ms Platona responded that the Department would have an interest across all therapeutic areas and in particular where the unit cost is likely to be high. Also, it would be useful to know where there are more co-dependents coming through in particular therapeutic areas, as well as follow-ons and biologics. It would also be interesting to know if new products were add-ons or replacement therapies.

Mr Delaat questioned whether there was another way of approaching this, asking of the top 20 disease areas, where is the biggest unmet need? The meeting discussed whether this was a useful approach for the Department.

The meeting discussed whether the creation of a phase two clinical trial database, with a longer timeframe, would be considered valuable. The meeting noted that at first look, a phase three database would seem more appropriate given that many phase two projects drop out.

The meeting heard that the Department appreciated the report and noted that a lot of work had clearly gone into its production. Medicines Australia asked for the Department's feedback on the direction and structure of the paper, any particular case studies the Department would like to see and any suggestions of other ways of looking at the data.

M13 A5 – The Department to provide feedback to Medicines Australia through the Horizon Scanning Working Group on: a) the direction and structure of the paper; b) any particular case studies for the next report; and c) any suggestions of other ways of looking at the data.

Item 4 – AMWG Workplan
The meeting agreed to go through items on the AMWG Workplan and discuss as participants considered appropriate.

Item 4.1 – Joint Medicines Policy Conference 2011
Ms Platona provided an update on planning for the conference. The meeting agreed that given the involvement of people in the room in the conference; a detailed update of planning would not be required. The meeting heard that 310 registrants had been recorded for the conference. Of these 275 were paying participants.

Item 4.2 – Key Activity Indicators
Mr Mitchell noted that the Key Activity Indicators (KAI) paper had been discussed by the PBAC and Medicines Australia Access subgroup. The next step was to put the paper onto

the website which was almost ready to go. The paper will next be discussed at the next PBAC-Medicines Australia meeting.

The meeting discussed the potential merits of disaggregating parallel processing applications. It was heard that this would be time consuming. The meeting mentioned the possibility of including an indicator around the end-to-end timeframe to list and heard that the Department did not want to create greater workloads at this time. The meeting heard that the paper presented represented the most feasible way of presenting this sort of key activity indicator information.

Mr Delaat asked if the AMWG could make a comment about the KAI in the joint communiqué and also provide a link to the website from the communiqué to draw more attention to the website.

M13 A6 – Key Activity Indicators to be mentioned in the joint communiqué from the 25 August meeting and a link to the relevant KAI website is also to be included.

Item 4.3 – Co-dependent Technologies Working Group

Mr Delaat noted that Medicines Australia was concerned about the lack of progress in this issue. Ms McNeill replied that a number of education sessions had been run through the Association of Regulatory and Clinical Scientists (ARCS). Transitional arrangements would start over the next 12-14 months. The meeting heard that Mr Mitchell had circulated information to be placed on the DoHA website to inform industry and other stakeholders. It was noted that there was a lot of behind the scenes work to progress this issue.

Ms Cutts noted that the Department wanted to work with Medicines Australia to help clarify emerging issues. The Department is proposing that in the transition period applicants can put in separate applications, possibly submitting to the PBAC first without submitting to the Medical Services Advisory Committee (MSAC).

Ms Cutts noted that the transition period finishes in November 2012, for the March 2013 meeting of the PBAC. It was noted that the material distributed contained a calendar to illustrate the need for timing alignments. Mr Richards offered that while the new Protocol Advisory Sub-committee (PASC) process might have a six-month lead time, overall the process will be faster.

The meeting heard discussion around previously understood plans to establish a Co-dependent Technologies Working Group to progress these issues. However that now the Department felt a less formal approach was more appropriate.

The meeting heard that Medicines Australia was interested to know if the process was likely to develop something that looked like a minor submission to the MSAC. Mr Richards responded that both MSAC and PASC had agreed that there should be such a minor submission pathway.

Mr Bruce noted that there are degrees of co-dependence and he asked if there was thinking in the Department about this matter. Mr Richards responded that the role of PASC is to determine the appropriate approach given the degree of co-dependance of PBAC and MSAC submissions and what the risks associated with particular approaches may be.

Mr Bruce and Mr Richards agreed to commit to discuss this work over coming weeks and months.

The meeting heard some discussion on whether the National Health Act allowed the PBAC to make a decision of the cost effectiveness of a medicine based on the cost effectiveness of a co-dependent technology.

The meeting noted that by the end of the year, the Department planned to have PBAC-like guidelines for the MSAC. The Department planned to have education sessions at ARCS at the start of 2012 to talk to potential applicants to the MSAC. The Department had been speaking to about 20 industry applicants, half a dozen of which had been providing feedback. Mr Richards noted that the Department appreciated the constructive two-way approach from member companies providing feedback.

The meeting considered next steps and agreed to continue discussions outside the AMWG. Mr Bruce agreed to set up meeting between Medicines Australia and the Department. It was heard that once this process has been finalised, education sessions for member companies would be needed. Mr Richards noted that the last ARCS meeting had provided information sessions with general information available at the time.

M13 A7 – Medicines Australia to organise a meeting with the Department to further progress work on co-dependent technologies.

Item 5 – First report to Parliament from AMWG on the MoU
The meeting noted the first annual AMWG Report on the MoU is due to be tabled in Parliament by the Minister and that due to the time required to table documents for the Parliament the report would need to be presented to the Minister for Health Ageing by October 2011.

Ms McNeill noted that a template was provided in the meeting papers and asked the meeting if they considered the approach outlined in the template appropriate. Mr Delaat noted that the approach to the report should be straightforward and that the template presented was good.

The meeting discussed the potential inclusion of the deferrals in the report and the Department would reserve judgement on this until the report was further developed.

Ms McNeill noted that the Department would appreciate collegiate work on the drafting of the report. The final project should be short, sharp and factual. Mr Bruce suggested the matter be taken off-line and a division of labour be decided upon. The meeting agreed to aim for presenting the final report to the co-chairs at their meeting in October. This would be an appropriate time before the document needs to be provided to the Minister to allow her clearance before tabling in the Parliament.

M13 A8 – The Department and Medicines Australia to determine a division of labour for the drafting of the report to Parliament.

Item 6 – Post-market surveillance implementation update
Mr Henderson noted that the measure was progressing well from the Department's perspective. From the *NPS Better Choices, Better Health* (NPS) point of view, they are about

to finalise a variation to MedicinesWatch. The NPS was also in the process of creating an ethics committee.

Item 7 – Other Business
The meeting endorsed the Draft Communiqué for the 19 May 2011 AMWG Meeting incorporating the changes proposed by Medicines Australia.

M13 A9 – The Department to upload the agreed joint communiqué for the 19 May 2011 AMWG meeting on the pbs.gov.au website.

M13 A10 – The AMWG Secretariat to prioritise the production and distribution of AMWG meeting action items.

Mr Delaat thanked participants and called the meeting to a close.