Access to Medicines Working Group - Work Plan

This work plan identifies three streams of work:

1. Current AMWG projects being undertaken directly by the AMWG.
2. Potential AMWG projects to be undertaken directly by the AMWG.
3. Other current MA-DHA activities of interest to AMWG.

Items are listed under the most relevant of the AMWG terms of reference.

a) the capacity to further streamline and coordinate processes to reduce the time it takes to list a medicine on the PBS

Current AMWG projects

1. Understand and map current processes up to PBS listing (from both government and industry perspectives) and identify key issues that impact on timeliness/efficiency.
2. Articulate options to improve these processes, taking into account cost recovery interaction and key performance indicators (KPIs) where necessary. Options include:
   a) Starting the listing process at an earlier point in the corresponding TGA process (noting potential for increased financial risk associated with increased PBAC deferrals and rejections, cost recovery issues, and possible increased workloads for contingency planning)
   b) Exploring opportunities for investment in earlier pre-submission dialogue, including to identify and seek to resolve technical and evidentiary issues about medicines under development to help influence design of trials which will eventually form the evidence base of PBAC submissions.
   c) Exploring streamlining options for the current PBS listing process, such as tiering of submissions with explicit criteria such as evidentiary requirements, cost to Government etc.

Other current MA-DHA activities

3. Development of key performance indicators for the PBS listing process, including further development to describe impact of serial submissions for a medicine on listing times.
4. Risk-sharing arrangements

b) possible impacts on the listing process of mandatory price reductions from 1 August 2008 for medicines on the new F2 formulary

Current AMWG projects

5. Identify and agree on possible impacts on the listing of new medicines.
   a) Report on outcomes of joint MA-DoHA workshops held in 2006 about the possible effects of price reductions for comparators on cost-effectiveness assessment of new medicines.
   b) Report on further work undertaken on possible effects of comparator price reductions.

c) Quantify the proportion of submissions in recent years where the comparator would be an F1 or F2 product.

d) Analyse data from PBAC evaluations in the period after the August 2008 price reductions take effect to determine any impacts on the listing of cost-effective new medicines.

6. Production of a joint MA – DoHA paper on the comparators issue.

a) Issues; and

b) Discussions of different options for their management if necessary.

c) the potential for improving clinical trial, economic and financial data to inform Pharmaceutical Benefits Advisory Committee (PBAC) and Pharmaceutical Benefits Pricing Authority (PBPA) decision making processes

Current AMWG projects

7. Issues paper on identifying uncertainty in the assessment of medicines for listing on the pharmaceutical benefits scheme - *Identifying the Issues and Gaps in current practices*

Other current MA-DHA activities

8. Evaluation of the impact of the 2006 PBAC Guidelines on PBAC submissions from both government and industry perspectives, including interaction with:

– Joint Policy Conference issues and outcomes (refer to Joint Policy Conference outcomes, Item 2: Standards of evidence and transparency);

– Coordination of and with Guidelines steering group activities;

– Workload from both government and industry perspective;

– Assessments of the extended use of both clinical and non-clinical data.

d) in collaboration with the PBAC, developing and articulating a set of principles for assessing evidence and information relating to new medicines and for improving the transparency of the decision making process

Potential AMWG projects

9. Identify what additional considerations are taken into account other than cost-effectiveness to improve understanding and transparency of decision making processes.

10. Develop protocols which enable the PBAC to explain publicly its controversial decisions ahead of the timeframes agreed for the standard processes for publishing PBAC outcomes.

Other current MA-DHA activities

11. Coordinate with ESC/MA's PBAC Guidelines revision steering group to examine risks and benefits of more timely public feedback from PBAC.

12. Report from Joint Policy Conference (JPC) oversight management committee on outcomes and work plan with respect to standards of assessing evidence relating to new medicines, including:

– Publishing a list of items for each PBAC agenda once these are accepted for evaluation.

– Enabling independent clinician and consumer input into PBAC considerations of submissions.

– Including the outcomes of “Item 8” PBAC agenda items as part of the processes to publish PBAC outcomes and PSDs (Item 8 consists of submissions to PBAC to request a change in price relativity).

e) the practical limitations to the evidence available to the PBAC to facilitate decision making around access to new medicines and the development of options to manage uncertainty in such situations

Current AMWG projects

13. Identify where the uncertainties are that hinder decision making, and identify potential solutions.

– For example, exploration of how “coverage with evidence development” might assist with the collection of additional post-listing data in order to enable a more confident PBAC recommendation to list in the future.

f) opportunities for informing and learning from the broader international debate about evidentiary requirements and trends in drug development to support the economic evaluation of new medicines

Potential AMWG projects

14. Identify framework and objectives for international engagement.

15. Assess opportunities at international forums to discuss health technology assessment consistent with this framework and where appropriate incorporate lessons into the Australian system.

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