



**Australian Government**

**Department of Health and Ageing**

# **WORKING TOGETHER TO IMPROVE THE PHARMACEUTICAL BENEFITS SCHEME**

## **Review of Post PBAC Processes Report**

**MEDICINES**  
*Australia*

---

BETTER HEALTH THROUGH RESEARCH AND INNOVATION

© Commonwealth of Australia 2004

ISBN: 0 642 82529 7

This work is copyright. Apart from any use as permitted under the *Copyright Act 1968*, no part may be reproduced by any process without prior written permission from the Commonwealth available from the Department of Communications, Information Technology and the Arts. Requests and inquiries concerning reproduction and rights should be addressed to the Commonwealth Copyright Administration, Intellectual Property Branch, Department of Communications, Information Technology and the Arts, GPO Box 2154, Canberra ACT 2601 or posted at <http://www.dcita.gov.au/cca>.

Publication Approval Number: 3521/JN8731



**Australian Government**  
**Department of Health and Ageing**

Dear Minister

The Review of post Pharmaceutical Benefits Advisory Committee (pPBAC) processes has been a collaborative effort between the Department and Medicines Australia to explore innovative options to reduce the time taken to list approved drugs on the Pharmaceutical Benefits Scheme (PBS) so that they are more quickly available to the Australian community.

The PBS is one of the vital parts of Medicare. Medicare aims to provide Australians with affordable access to cost-effective and high quality health services. The PBS is recognised world wide as a leader in evidence-based evaluation of pharmaceuticals and as an effective subsidy program of great value to the community.

The Review did not open up for debate the fundamental policy for either the Pharmaceutical Benefits Advisory Committee evaluation of drugs proposed for PBS listing or the Pharmaceutical Benefits Pricing Authority in determining pricing. Instead it provided the Department and Medicines Australia with an opportunity to work together to develop a more effective, efficient and transparent listing process within these policy settings.

We have, together, formed the Reference Group to lead this work. We are now pleased to present to you the attached final report, “Working Together to Improve the PBS”. We look forward to your response to the recommendations it presents.

The Review’s Project Team gathered and analysed information about pPBAC processes and the relationships and interaction between stakeholders. All considerations in this process recognised the Department’s important role in ensuring that drugs listed on the PBS are effective and affordable, as required by the Government’s National Medicines Policy.

The review has advanced the relationship between the Department and the pharmaceutical industry. Review participants gained new insights into the goals, pressures, and opportunities that drive each other’s agendas. Stakeholders contributed many valuable perspectives and insights.

The Review started well before the negotiations for the Australia-US Free Trade Agreement (AUSTFA). We were not surprised that similar issues relating to process improvements and increasing the transparency of the PBS listing process have arisen in both contexts. Implementation of the Review’s recommendations will directly assist the Government meet its new obligations under the AUSTFA.

We look forward to working with you as you consider the findings of the review, its recommendations, and implementation of the changes you wish to progress.

Yours sincerely

Philip Davies  
Deputy Secretary  
Department of Health and Ageing

Jeays Lilley  
Board Member  
Medicines Australia

# WORKING TOGETHER TO IMPROVE THE PHARMACEUTICAL BENEFITS SCHEME— Review of post PBAC processes

1. Setting the scene .....	2
2. Describing the review .....	3
3. Developing the goals .....	3
4. Making recommendations .....	5
Goal 1: Streamline pPBAC processes and reduce the time to listing .....	5
Goal 2: Focus on critical areas for agreement .....	8
Goal 3: Take partnership approaches and build relationships .....	11
Goal 4: Emphasise transparency in pPBAC processes and clarify the PBPA's roles and responsibilities .....	14
Goal 5: Develop internal capabilities.....	15
Goal 6: Implementing change and measuring progress.....	16
5. Summarising the outcomes.....	17
6. Taking account of resources and risks.....	18
Managing and resourcing issues .....	18
Looking at risks.....	18
7. Working together for the future.....	19

## Attachments

A: Diagrams of current PBS listing process and proposed flexible three-tiered approach

B: Membership

C: Terms of Reference

## List of short forms

DoHA	Department of Health and Ageing
HIC	Health Insurance Commission
MA	Medicines Australia
PBAC	Pharmaceutical Benefits Advisory Committee
PBB	Pharmaceutical Benefits Branch
PBPA	Pharmaceutical Benefits Pricing Authority
PBS	Pharmaceutical Benefits Scheme
pPBAC	post Pharmaceutical Benefits Advisory Committee
TGA	Therapeutic Goods Administration

## 1. Setting the scene

The Pharmaceutical Benefits Scheme (PBS) is one of the vital parts of Medicare. Through Medicare, the Australian Government aims to provide all Australians with access to cost-effective and high quality health services. The PBS is recognised world wide as a leader in evidence-based evaluation of pharmaceuticals and as an effective subsidy program of great value to the community.

The government's National Medicines Policy, announced in 1999, guides the PBS. The policy was developed to ensure timely access to medicines that Australian consumers need, and at a cost that individuals and the community can afford.

The policy also states it is essential that medicines meet appropriate quality standards and that there is a rational funding system and a viable local medicines industry.

However, in recent years, processes for listing medicines for government subsidy via the PBS have become very complex. The time it takes to have some complex and high-cost drugs listed has increased and the decisions about which drugs to fund have become very challenging.

Of particular concern to industry, doctors and consumer groups is the perceived delay between Pharmaceutical Benefits Advisory Committee (PBAC) recommendation and listing for drugs, particularly those which will cost the PBS more than \$10 million per year (High Cost Drugs or HCDs).

The process for listing medicines on the PBS is complex. As part of the PBS processes, the PBAC receives drug company applications for listing. If the PBAC recommends a drug be considered for listing, the Pharmaceutical Benefits Pricing Authority (PBPA) then considers the pricing element and recommends either a ceiling price or an acceptable price range for a drug.

The PBPA secretariat uses this recommendation to negotiate with the sponsor company, including an agreement on price. For drugs that require Cabinet approval for listing, Cabinet submissions and detailed costings are prepared and agreed. When these steps are complete, Cabinet's recommendations are considered by the Minister in deciding whether to approve or reject the drugs for PBS listing.

Once listing approval is given, departmental systems are updated, legislative instruments completed and the approved drugs are included in the next issue of the Schedule of Pharmaceutical Benefits.

This review considers the latter part of this total process for listing. The post PBAC (pPBAC) processes include all the activities following a positive recommendation from the PBAC for listing on the PBS (see **Attachment A** for information about the activities required to list a drug on the PBS). The Review did not open up for debate the fundamental policy for either the PBAC evaluation of drugs proposed for PBS listing or the PBPA in determining pricing.

## 2. Describing the review

In August 2003, the Australian Government Department of Health and Ageing (DoHA) and Medicines Australia (MA) (representing the pharmaceutical industry) commenced a joint review of the pPBAC processes. A Reference Group comprising of Mr Philip Davies (Deputy Secretary, DoHA) and Mr Jeays Lilley (board member, MA) oversaw the review. The review Project Team included senior members of DoHA (from the Pharmaceutical Benefits Branch (PBB)) that administers the PBS, MA (represented by senior members of pharmaceutical companies), and an independent facilitator, Dr Gary Saliba, experienced in business analysis and change management (Full membership list is at **Attachment B**).

In line with the review's terms of reference (see **Attachment C**), the broad aim was to:

“... design a streamlined process/arrangement that is best positioned to deliver efficient, effective, certain and transparent outcomes for government, the pharmaceutical industry, prescribers and the community ...”

In setting up the review, DoHA and MA worked together to:

- explore innovative options to reduce the time taken to list approved drugs on the PBS so that they are more quickly available to the Australian community
- look at the best ways to provide greater clarity and transparency about the processes for the pharmaceutical industry, prescribers and Australian community and hence to improve confidence in decisions and outcomes
- improve the quality of the pPBAC processes
- build better and stronger relationships between the department and industry.

The review focused on the listing processes for new products, and products that have a change in listing, after a positive recommendation from the PBAC. The activities of the PBPA were also examined as part of the review.

The review did not consider processes for products that do not need a PBAC recommendation for listing, such as additional brands of existing items. Also, the processes for periodically assessing existing products were not examined. Activities undertaken before PBAC consideration were not part of the review's scope. However, activities that commenced prior to the PBAC meeting, and continued throughout the pPBAC processes, were included in the review.

## 3. Developing the goals

The review's Project Team gathered information about pPBAC processes and information about the relationships and inter-action between PBB and the pharmaceutical industry.

The facilitator interviewed individuals and representatives of organisations involved in pPBAC processes. The Project Team used this information to analyse the activities and underlying dynamics of the pPBAC processes to identify areas for improvement. Based on this analysis, six goals to improve the processes were identified. These are:

**Goal 1.** Streamline pPBAC processes and reduce the time to listing

**Goal 2.** Focus on critical areas for agreement

**Goal 3.** Take partnership approaches and build relationships

**Goal 4.** Emphasise transparency in pPBAC processes and clarify the PBPA's role and responsibilities

**Goal 5.** Develop internal capabilities

**Goal 6.** Implement change and measure progress

**Note:** The review's working papers include greater detail on the impetus for this review and its objectives and scope. The working papers also provide explanations about the process of analysis used to inform the recommendations.

## 4. Making recommendations

### GOAL 1: STREAMLINE pPBAC PROCESSES AND REDUCE THE TIME TO LISTING

#### Issues—slow and inflexible listing processes

Whatever the complexities for pricing arrangements, under the current system all new drugs are required to undergo the same pricing and listing processes, with additional steps for HCDs. There is no fast-tracking of the simplest submissions. For example, all products must be referred to the PBPA before pricing is finalised, even those where there are no pricing issues to be resolved. This can mean an inefficient use of PBB resources and can delay listing products for those where there are no outstanding issues to resolve.

**Recommendation 1:** Redesign pPBAC processes to recognise the complexities of drug submissions. This involves introducing a three-tiered process:

- a) Tier 1 is a fast-track process where, for agreed submissions, a PBPA recommendation is no longer required (thus significantly reducing timelines)
- b) Tier 2 aligns closely with the current process
- c) Tier 3 is a process designed to deal with complex submissions, including all of those that will require a Cabinet submission.

The full benefits of introducing the three-tier process will not be realised unless/until the redesign of PBB business and IT systems is completed.

**Recommendation 2:** Criteria and detailed steps for three tiers to be developed by PBB in consultation with industry.

#### *Anticipated outcomes*

- make submission processes more flexible and reduce the time to list PBS-approved products (**Attachment A** includes diagrams showing the expected steps in each tier)

---

#### Issues—timing, efficiency and understanding of Cabinet submission process

Since 2002, the government has required consideration by Cabinet of HCD proposals before listing. The process of preparing a submission for Cabinet is an internal government activity. It involves detailed costing, clearances by senior executives in DoHA, agreement with the “central agencies” of Treasury, Department of Finance and Department of Prime Minister and Cabinet, and decisions by the Prime Minister and Cabinet office about the timing for consideration by Cabinet.

As the process is relatively new, and has been developed quickly, industry does not have a great understanding of how it works and concern has arisen, strengthening through 2003. Some public accusations have been made by consumer advocacy groups that the government holds up the submission process to delay the impact of new expenditure on the PBS. Better understanding is needed.

**Recommendation 3:** PBB develop an efficient process for developing Cabinet submissions.

**Recommendation 4:** PBB develop and disseminate a clear communications strategy for this process.

*Anticipated outcomes*

- improve efficiency of PBB Cabinet submission preparation
  - build industry understanding of the Cabinet process
  - improve transparency by communicating the status of departmental submissions, if appropriate
- 

**Issues—delayed listing due to inflexible PBS Schedule processes**

PBS publishing and distribution processes are outdated, paper-based and labour intensive. As well, the paper-based Schedule of Pharmaceutical Benefits publication process severely limits the ability to introduce quicker listing cycles.

**Recommendation 5:** Redesign/modernise PBB business and IT systems to enable PBS-approved drugs to be listed one month after complying with all conditions.

**Recommendation 6:** Streamline and enhance on-line PBS Schedule publishing to introduce a monthly PBS publishing cycle and make information available directly to users.

*Anticipated outcomes*

- reduce the time for listing a medicine on the PBS
  - introduce monthly cycle for listing PBS-approved medicines
- 

**Issues—unnecessary TGA sample testing**

Marketing approval for all medicines is granted by the Therapeutic Goods Administration (TGA) following a paper-based assessment. All items entered onto the PBS must have TGA marketing authority prior to their listing. In some cases, eg. vaccines and other biological medicines, TGA applies a condition of approval whereby product sponsors must submit samples for analysis prior to batches being distributed in Australia. Other products are included in TGA's risk-based post-market testing program.

Around 80% of new listings recommended by the PBAC are required to pass TGA laboratory testing. Rebranded products and products already tested by TGA are not retested as part of this process. Also, where the product is supplied in multiple strengths, then usually only one strength is selected for testing.

These post-PBAC testing arrangements have been in place for many years and there is an opportunity to review them for possible efficiency improvements.

**Recommendation 7:** PBB investigate the possibility that the TGA marketing approval processes are sufficient for PBS approved drugs.

***Anticipated outcomes***

- reduce redundant processes
- maintain confidence in quality control through existing TGA marketing approval processes

## GOAL 2: FOCUS ON CRITICAL AREAS FOR AGREEMENT

### Issues—disagreements about patient numbers, the target population (that is, ‘restrictions’) and pricing

In the listing process, agreement on a number of issues can take significant time. This can lead to listing delays as well as very short timeframes in which to develop and distribute prescribing information for doctors.

‘Hot spots’ for disagreement are wordings about prescribing restrictions; pricing arrangements for medicines with a high financial risk; and estimates of patient numbers (including target population, growth factors, and so on).

Discussions about the hot spots often begin only **after** a positive PBAC decision. Earlier discussion on issues (for example, before the company submits a PBAC submission) may result in earlier agreements once a positive PBAC decision is reached.

**Recommendation 8:** PBB to give companies the option to have additional discussions starting at earlier stages - throughout pre and pPBAC processes.

#### *Anticipated outcomes*

- achieve earlier agreement on ‘hot spot’ areas
- reduce the pPBAC time taken for agreement
- increase the number of applications approved in minimum time
- improve confidence in the processes and quality of negotiations

---

### Issues—time taken to finalise wording of restrictions

Resolution on restrictions is required for both sponsor companies and government to ensure certainty when negotiating pricing arrangements and finalising utilisation estimates. The timeframes for resolution are unclear and there is variation in the complexity of restrictions for some drugs. More complex restrictions require extra consultation with expert clinicians and other stakeholders.

In addition, recent experience of complex restrictions has shown that difficulties can arise for the Health Insurance Commission (HIC), prescribers and for some patients in managing the operational side of new drug listings when restrictions apply. Sponsor companies have a vital interest in the restrictions and detailed knowledge of the product that can assist in finalising restrictions which are operationally sound and deliver the required results.

Prescribers need clear, unambiguous guidelines and practical processes, especially where they have to seek an authority from the HIC before they can issue a prescription to their patient. The HIC needs to ensure that the right patients are getting access to the drugs and that prescribers are not writing inappropriate scripts. It must be able to audit and report on the actual practices of drug use over time. The restrictions need to be finalised

at an early enough stage for the operational issues and prescriber education to be well managed.

**Recommendation 9:** Finalise restrictions wording within 15 to 30 days of PBAC meeting by:

- a) discussing potential restrictions in pre-submission meetings
- b) establishing two categories of restrictions in recognition of restriction complexity (ie standard restrictions and complex restrictions - requiring extra consultation with expert clinicians and other stakeholders)
- c) encouraging PBB/MA/HIC to work together to introduce common templates in implementation and communication of restriction wording
- d) HIC providing relevant time and cost implementation data within five working days of finalisation of restrictions wording.

### *Anticipated outcomes*

- enable faster resolution of restrictions issues
- increase understanding of restrictions
- provide information for education materials earlier
- develop earlier costings for, and set up of, HIC operations

---

### **Issues— failure to agree about patient numbers and growth in target population (that is, ‘usage estimates’)**

There are often tensions between companies and PBB over the usage estimates for new drugs coming onto the PBS list. This is not surprising since there is inherent uncertainty in such estimates. PBB has a need to assess the financial impact on the PBS and may, in some cases, believe that there are more patients likely to be eligible for the drug than claimed by the company, or that there is more risk of use beyond the restriction than does the company. The players may take into account different data sources in estimating likely usage. This can result in a lack of clarity around estimates and a lack of confidence in the process.

The team within PBB that provides advice to the Drug Utilisation Sub-Committee (DUSC) of the PBAC is known as the DUSC secretariat. Their role includes assessing likely usage numbers and patterns over time for new drugs proposed for listing. They also monitor and report on the actual usage patterns of drugs on the list and advise the PBAC of any unexpected trends. This role is separate from the role of the pricing section within PBB, but the latter group must rely on the DUSC usage estimates when it comes to costing the impact on PBS for government consideration. The pPBAC processes certainly works best when there are early and continuing consultations between the company and the DUSC secretariat. If differences of view cannot be resolved, government needs advice about the difference and the reasons for it.

**Recommendation 10:** Work towards earlier agreement of usage estimates through timely consultations about methods used to calculate, and establish patient population numbers and their growth patterns.

**Recommendation 11:** Where usage estimates cannot be agreed, PBB and the sponsoring company continue to pursue agreement by considering innovative pricing arrangements to apportion financial risk.

*Anticipated outcomes*

- reach earlier agreement on usage estimates
  - improve confidence in usage estimates processes
  - improve relations between PBB and industry
- 

**Issues—late agreement on prices and pricing arrangements**

Discussions on these issues often commence only after a positive PBAC decision. Earlier discussion on issues (eg. prior to company submitting an application to the PBAC) may result in earlier draft agreements and hence reduce time to listing. While any draft agreements would not be binding or final, because they would depend on positive recommendations from the PBAC and endorsement from the PBPA, they would be able to be presented to these bodies as proposals that appear acceptable to the sponsor and the PBPA secretariat.

Limited information with respect to the reasons for decisions from the PBPA is available to the sponsor company. There is also limited capability for companies to learn about different pricing arrangements that are both acceptable to government and suitable for different products. Both these factors contribute to the quality and speed with which pricing negotiations are finalised.

**Recommendation 12:** Commit to early and ongoing pricing discussions (starting at the latest one week after PBPA meetings); providing more detail to sponsors about PBPA recommendations (as nominated by the PBPA); and developing a joint ‘toolbox’ of pricing options for use by all companies.

*Anticipated outcomes*

- achieve earliest possible agreement on prices
- reach the most suitable pricing agreements
- improve transparency regarding reasons for PBPA recommendations, while noting constraints on provision of PBPA minutes
- improve industry knowledge of pricing options

## **GOAL 3: TAKE PARTNERSHIP APPROACHES AND BUILD RELATIONSHIPS**

### **Issues—lack of shared vision and poor perceptions about flexibility**

Currently, the industry, government and other stakeholders seldom discuss the intent of the system and how the processes ‘fit’ with the intent. The processes are perceived as limited in responding to change and some of the players have been slow to recognise and adapt to change.

Industry perceives an informal or ad hoc approach to change, which has led to confusion and ambiguity. Within industry, knowledge varies significantly and this is reflected in its submissions.

There is also limited communication throughout the pPBAC processes. The communication takes a variety of forms (verbal, email, official correspondence). This factor also contributes to a lack of understanding about the processes and timing.

Taking account of resource constraints, including the acceptable use of taxpayers’ money, there is room to improve relationships between industry and government and to achieve the common goal of delivering affordable medicines to consumers.

**Recommendation 13:** PBB and MA to 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 MA sharing information around PBS market factors and trends
- c) PBB and MA developing indicators to assess the effectiveness of pPBAC processes in achieving their objectives
- d) PBB, MA 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.

### ***Anticipated outcomes***

- increase knowledge and understanding of strategic PBS issues, support systems and processes
- improve relationships between the players
- change negative perceptions about the processes
- increase willingness by the players to take initiatives and adapt to change
- provide a forum for strategic discussions

---

### **Issues—lack of regular and formal discussions**

Industry believes that there is not enough formal opportunity to raise concerns and consult about the policy and procedures adopted in the pPBAC processes. There is also limited opportunity for individual companies to learn from previous submissions, or to discuss future directions for the company and how they relate to the PBS.

**Recommendation 14:** Give individual pharmaceutical companies the opportunity to meet each year with the PBB to discuss issues that may be confidential or of interest to the company (and PBB), such as pPBAC processes generally and past submissions.

**Recommendation 15:** Realign resources within PBB to establish an industry liaison group that provides a ‘first point of contact’, and proactive and integrated service for pharmaceutical companies across the range of industry needs.

***Anticipated outcomes***

- give PBB and industry the opportunity to learn from each other’s experiences
  - lead to better forward planning
  - improve communication between PBB and pharmaceutical companies
  - maintain continuity of knowledge within PBB about industry and individual company experiences
- 

**Issues—lack of company understanding of PBB business**

While many companies have staff regularly dealing with PBS issues, some do not fully understand pPBAC processes, or how the government reaches PBS listing decisions. As well, some companies experience high staff turnover in areas where an understanding of PBS processes is important. At the moment, there is no ongoing education process about the PBS for industry staff.

**Recommendation 16:** PBB and MA to develop comprehensive education programs on all aspects of pPBAC processes by:

- a) MA identifying key industry needs for education programs
- b) MA exploring additional avenues for industry education
- c) jointly preparing materials for the education programs
- d) regularly reviewing programs
- e) funding programs through participant attendance.

***Anticipated outcomes***

- improve the quality of submissions
  - increase confidence in the processes
  - strengthen relationships through wider understanding
- 

**Issues—outdated and inconsistent communication**

Sponsor feedback indicates that some messages from PBB are not formally advised and/or that the timing is variable and unclear. They say that they would like formal, written statements at key points in the decision-making process. While there are security concerns still to resolve, most companies prefer official communication via email or in writing.

**Recommendation 17:** Improve the DoHA/industry relationship by using more open communications through PBB and industry developing agreed, open and transparent communication protocols, and through PBB providing written communication (by email or letter) at agreed milestones in the processes.

*Anticipated outcomes*

- improve transparency in progress of sponsor applications
- ensure common understanding of agreements reached
- improve the quality of submissions
- help sponsors understand when progress updates will be available

## **GOAL 4: EMPHASISE TRANSPARENCY IN pPBAC PROCESSES AND CLARIFY THE PBPA'S ROLES AND RESPONSIBILITIES**

### **Issues—processes, roles and responsibilities are poorly understood**

Industry has concerns about the transparency of pPBAC processes. There is a lack of understanding about the roles, responsibilities, accountabilities and processes of the PBPA now and into the future. As well, the role of the DUSC secretariat and the pricing section in finalising usage estimates and costings needs clearer explanation.

There is confusion about the pricing authority's role in changing or modifying policies and procedures. Companies would like to see all non-confidential PBB advice that goes to the PBPA about their own submissions.

At the same time, the industry has some negative perceptions about PBB's role in pPBAC processes. This stems from what industry sees as an ambiguity about roles in PBB, for example how the branch provides expert advice and support for decision-making. Industry has a perception that this is detrimental to procedural fairness.

**Recommendation 18:** Provide greater transparency in PBPA processes by documenting and clarifying the roles, responsibilities and accountabilities of the PBPA as an organisation, and of its members.

**Recommendation 19:** Articulate clearly the roles and responsibilities of PBB support staff, and acknowledge the need for continuity in the processes.

**Recommendation 20:** Any additional, non-confidential information that is forwarded to the PBPA also be provided to the sponsoring company, thus giving sponsors the opportunity for further input in advance of authority meetings. (**Note:** This will add time to the listing process.)

**Recommendation 21:** PBB needs to clarify the roles, responsibilities and accountability of its work around usage estimates and price negotiations. There needs to be a clear and transparent organisational structure for advice on usage estimates.

### ***Anticipated outcomes***

- address perceptions about the transparency of the PBPA and pPBAC processes
- strengthen negotiations and the relationship between industry and PBB
- improve the alignment of influence and decision-making within pPBAC processes to improve industry perceptions of procedural fairness

## GOAL 5: DEVELOP INTERNAL CAPABILITIES

### Issues—inadequate industry expertise, and skills and knowledge gaps

Over the years, the PBAC submission and pPBAC listing processes have become more complex in their clinical, economic and financial data requirements. As well, the number of stakeholders involved in the processes has increased (because of more products requiring Cabinet consideration). Both PBB and industry recognise that the skill and experience mix required to ensure an effective and efficient listing process may not have kept pace with the changes.

Industry's internal capability and skills have not sufficiently adapted to changes in the pPBAC processes. In part, this is due to some process changes being developed informally. As well, there can be few learning opportunities for those companies that only make occasional submissions.

Industry's ability to change is influenced by a shortage of available expertise in industry to fill key positions. This can lead to significant gaps in knowledge of processes and requirements for submissions, and also to gaps in skills to meet these requirements.

In addition, PBB acknowledges gaps in skills and capability among its own staff, particularly because of staff turnover.

**Recommendation 22:** Industry and PBB further develop technical and negotiation skills by identifying/reviewing required skill sets and filling gaps.

### *Anticipated outcomes*

- improve industry and PBB internal skills and knowledge
- fill capability gaps
- build the relationship between PBB and MA

## GOAL 6: IMPLEMENTING CHANGE AND MEASURING PROGRESS

### Issues

Adequate resourcing for implementing and continuing support of the review's recommendations is critical to achieving outcomes, noting that the timing and priority given to implementing change will depend on the resources available.

Assessing and evaluating the review outcomes will provide important pointers for future improvement work. Regular reporting at agreed milestones against performance indicators, both quantitative and qualitative, would form a solid foundation for assessing effective implementation of the review recommendations.

**Recommendation 23:** Support implementation of agreed pPBAC processes and other changes by establishing a joint PBB/industry Implementation Group to develop a project plan that includes resourcing and timing issues, performance criteria and milestone targets.

**Recommendation 24:** Develop specific performance criteria to assess the effective implementation of the review recommendations to achieve the anticipated outcomes of the review. Develop the criteria in consultation with MA and discuss them each year at the PBB/MA/PBPA strategic meeting.

**Recommendation 25:** Conduct an evaluation of the pPBAC review within 12 months of starting to implement the recommendations.

**Recommendation 26:** Hold regular reviews to ensure that the changes continue to be effective and to identify how processes can be improved over time.

### *Anticipated outcomes*

- provide a way to implement the recommendations
- measure the outcomes against the review's goals

## 5. Summarising the outcomes

The 26 recommendations of this report were developed to:

- **reduce time to list a drug by:**
  - introducing flexible, three-tiered pPBAC processes that will mean new products, with the exception of those that require Cabinet consideration, will take a maximum of four months to list after receiving a positive PBAC recommendation. For about 25 per cent of these, the time will be six to eight weeks
  - modernising PBB information technology systems and enhancing on-line publishing processes, to enable monthly listing cycles
  - providing earlier consultations between PBB and industry prior to lodgement of PBAC submissions, to achieve earlier agreement in areas that can cause delays.
  
- **increase clarity and confidence in pPBAC processes through:**
  - clarifying roles and responsibilities throughout pPBAC processes, to address underlying tensions and concerns between industry and DoHA
  - expanding consultation and liaison between PBB and industry, to support industry through the processes particularly in times of change.
  
- **improve quality of pPBAC processes by:**
  - developing joint and individual training and education programs which will help to improve the quality of submissions, increase knowledge of the process, and build understanding of change
  - further developing PBB and industry internal capability, by identifying and improving technical and negotiation skills.
  
- **strengthening networking and creating a shared vision by:**
  - providing better communication channels and holding education forums to improve the interaction between industry and DoHA.

## **6. Taking account of resources and risks**

### **Managing and resourcing issues**

Once agreement is reached to implement the recommendations, PBB and MA will set up an Implementation Group to set directions and priorities for implementing the recommendations, agreeing on performance indicators and overseeing the progress (see Recommendations 23 and 24).

The Implementation Group will also identify those recommendations that require a joint DoHA/MA effort, and those that only require industry **or** departmental involvement. DoHA will establish a team within PBB to manage implementation of the recommendations. MA will also need to provide dedicated resources to implement the review recommendations. In addition, all stakeholders will be consulted as appropriate.

### **Implementing the recommendations**

Depending on resourcing arrangements, many recommendations can be implemented within 12 months. These include designing the streamlined, three-tiered business processes; developing education packages; putting in place expanded consultation arrangements (including the industry liaison group); clarifying roles and responsibilities where specified; and working through the recommendations to address issues in the critical areas for agreement. The recommendations that require redeveloping information technology (IT) systems will take longer to complete. These include the development of a modern on-line PBS information service with monthly updates.

### **Looking at risks**

Taken as a ‘package’, the recommendations are designed to deliver improvements in processes, remove unnecessary impediments, and improve timely access to affordable medicines. As the recommendations are designed as a package, total or partial rejection of the report will lessen opportunities to fully meet the review’s objectives.

For example, the introduction of a three-tiered process has the potential to reduce timelines as a PBPA recommendation would not be required for Tier 1 drugs. However, this potential will not be realised if, for example, the PBB publishing processes are not modernised and the Schedule continues to be published every three months (instead of a monthly publishing cycle as recommended by the review).

Without improvements, the increase in sophisticated and complex drugs might exacerbate and lengthen existing listing processes. Given that complex or high-cost drugs already take a long time to list, the imperative today is to ease the pressure on the listing processes.

## **7. Working together for the future**

The pPBAC review process achieved some remarkable outcomes. It saw the government and the pharmaceutical industry working together in true partnership to improve the timely access to medicines that Australian consumers need, at a cost that individuals and the community can afford. The review also engendered a spirit of partnership, collaboration and learning. In themselves, these were significant and positive achievements.

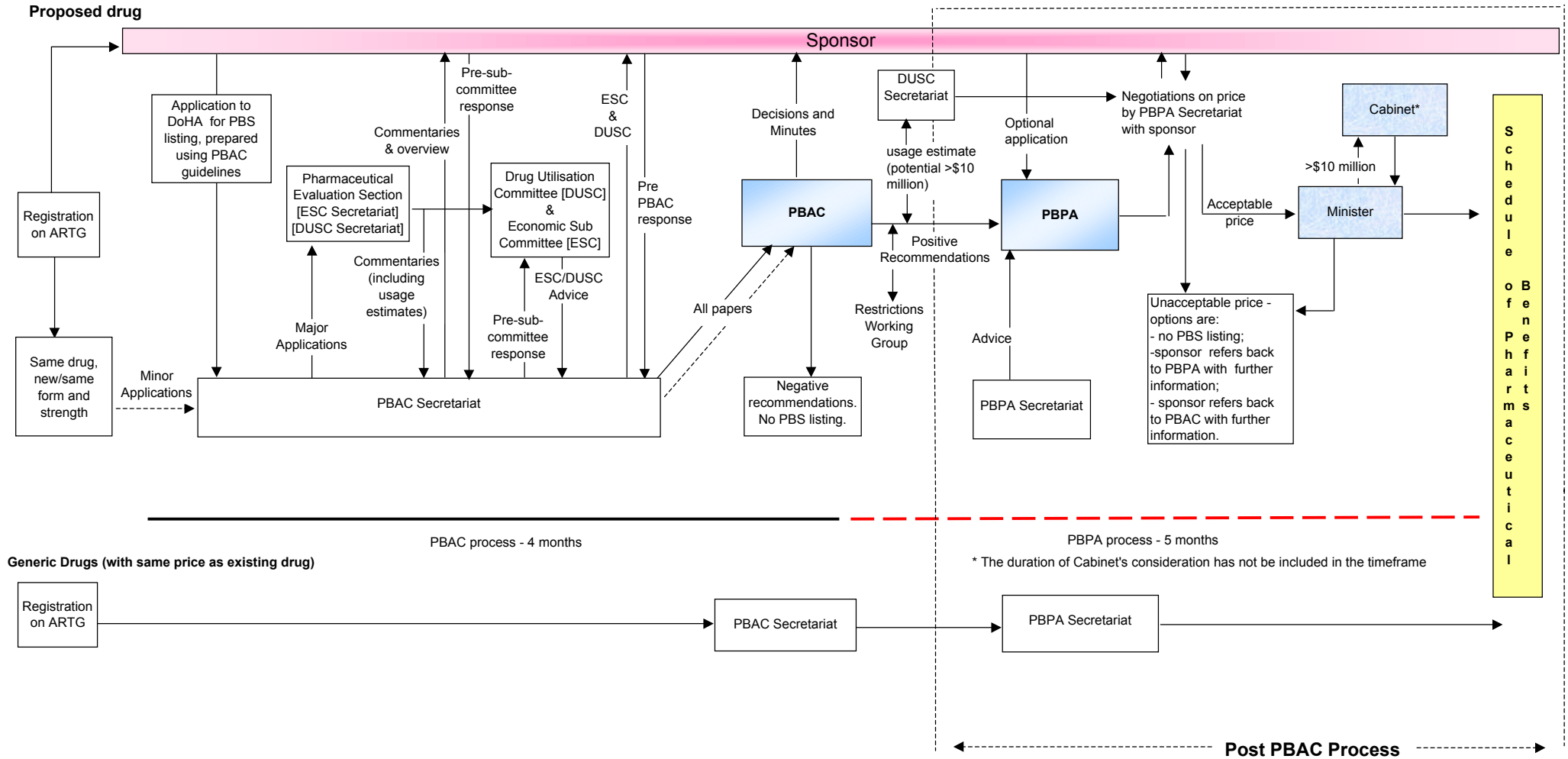
The review participants agree that from the review process they gained new insights into the goals, pressures, and opportunities that drive each other's agendas. They experienced a new understanding about the differences and synergies that exist between them. Further, the review created a climate of unprecedented collaboration and cooperation, and this is reflected in the report's recommendations.

Turning these recommendations into practical outcomes - and meeting the review's objectives - will provide the opportunity to extend this partnership approach to other participants in pPBAC processes. The Project Team believes this would bring benefits to all the players - the government, the department, the pharmaceutical industry and, not least, the Australian community.

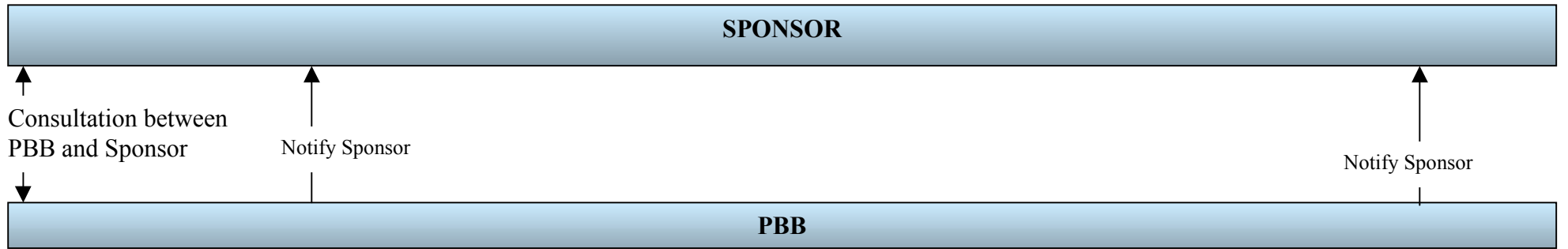
Recommendations include working together to develop a shared vision for the future - that is, to contribute to our aim of continuing to provide affordable and accessible pharmaceuticals in the years to come.

If implementation is measured as successful, it makes good sense to build on the review process. For example, some of the innovations in this report (such as fast-tracking applications that meet strict criteria) could be applied to other areas of the system (such as how we consider and recommend drugs for PBS listing). Indeed, the innovations could be used in a review of the whole PBS system (pre- and post-PBAC) to develop a consistent, effective and integrated system for considering and listing medicines on the PBS for government subsidy.

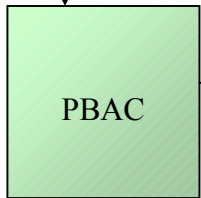
Process to gain PBS listing for registered drugs



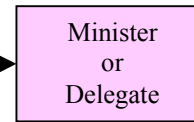
**Post PBAC Process - TIER 1**



Tier Category & Agreement-in-principle



Recommendation (no changes)



Approval

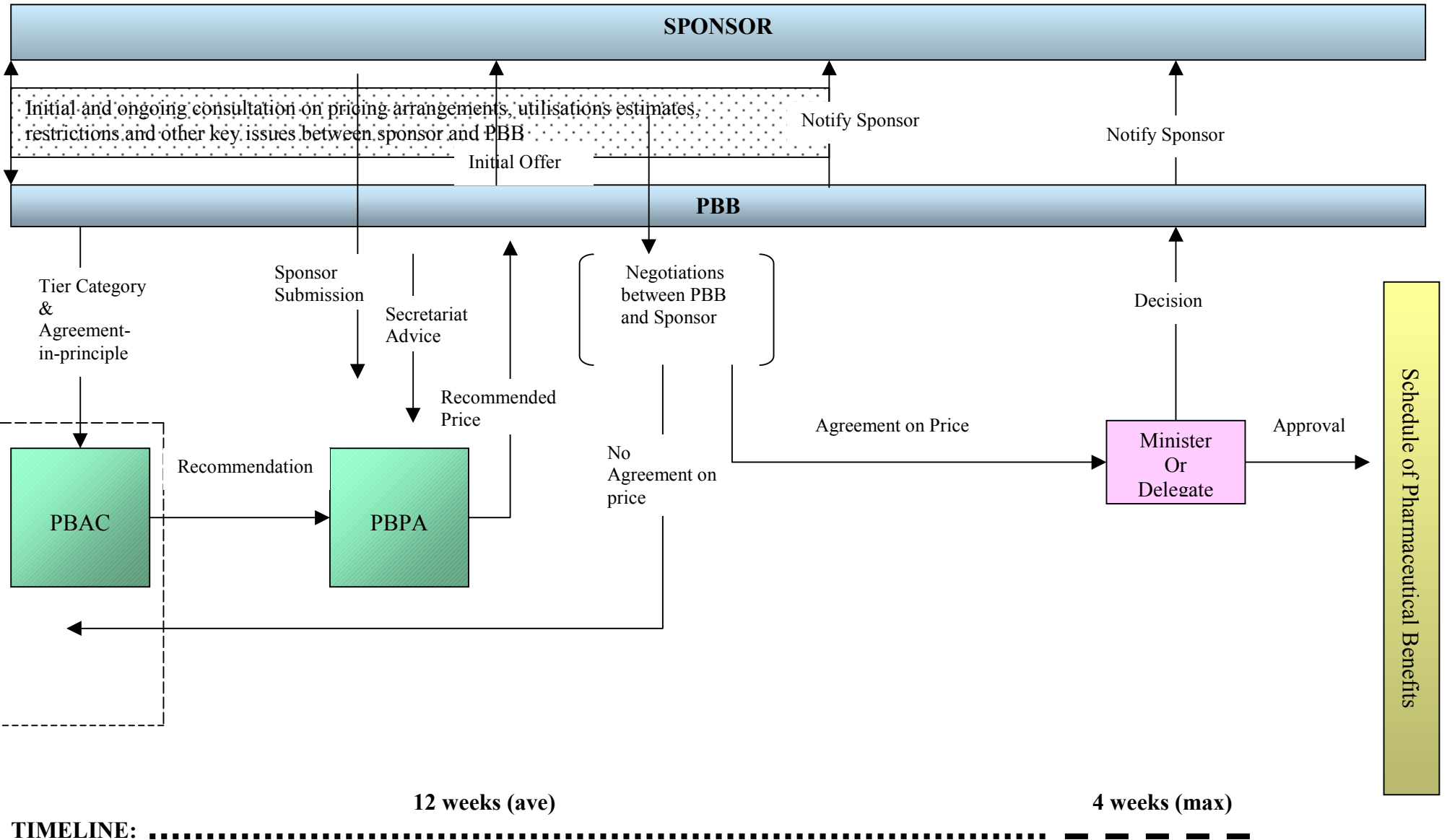


4 weeks

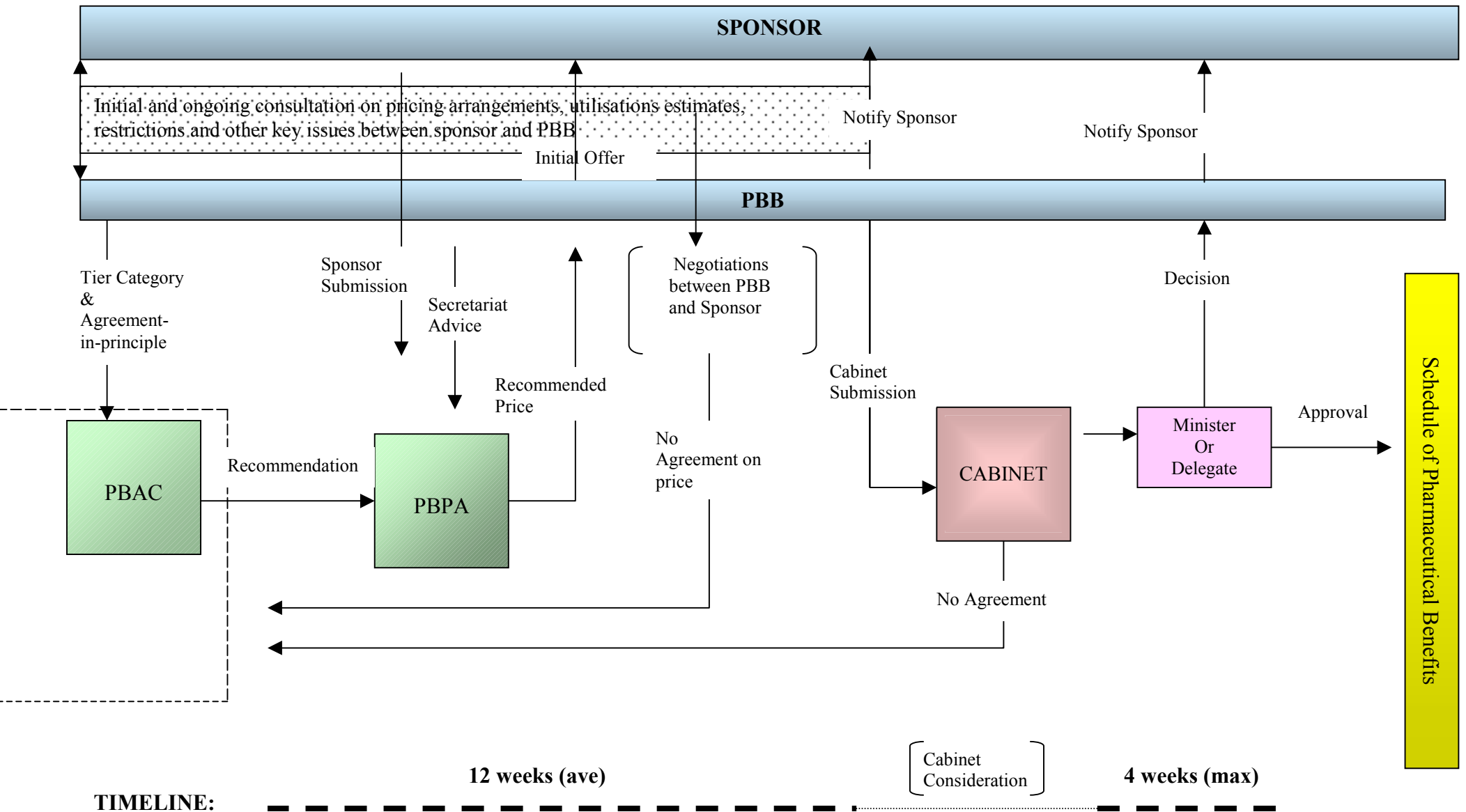
**TIMELINE:**



# Post PBAC Process - TIER 2



**Post PBAC Process - TIER 3**



## **Attachment B**

### **Membership**

#### **Reference Group**

Philip Davies, Deputy Secretary, Department of Health and Ageing

Jeays Lilley, Board member, Medicines Australia

#### **Project Team**

Des Threlfall, Department of Health and Ageing nominee, Pharmaceutical Benefits Branch, Pharmaceutical Advisor

Judith Forster, Department of Health and Ageing nominee, Pharmaceutical Benefits Branch, Director of Pharmaceutical Policy Section

Michelle Burke, Medicines Australia nominee, Bristol-Myers Squibb Pharmaceuticals, Director, External Affairs

Steve Crowley, Medicines Australia nominee, Janssen-Cilag, Director for Reimbursement and Pricing

Dr Gary Saliba, Independent consultant, Strategic Journeys

### Review terms of reference

The Review of the Post Pharmaceutical Benefits Advisory Committee (pPBAC) Processes was a joint project involving the Australian Government Department of Health and Ageing and Medicines Australia. Both organisations agreed on the ways the review was conducted.

The review's terms of reference were:

The Review will examine and make recommendations on the pPBAC listing process (including pricing) of medicines for subsidy purposes following a positive recommendation for listing on the Pharmaceutical Benefits Scheme (PBS) by the PBAC.

The main objective of this review is to advise on any necessary pPBAC changes to the existing arrangements for achieving PBS reimbursement which would improve the efficiency and effectiveness of the entire process in order to achieve earliest possible subsidised access for consumers to cost effective medicines, whilst minimising the regulatory burden on industry.

1. Examine the processes for consideration of drug pricing for subsidy purposes and other related listing processes following a positive recommendation for listing on the PBS by the PBAC and to identify the most appropriate arrangements for the future. The goal is to design a streamlined process/arrangement that is best positioned to deliver efficient, effective, certain and transparent outcomes for government, the pharmaceutical industry, prescribers and the community, including the achievement of a maximum four-month timeframe from date of positive PBAC recommendation to available subsidy.
2. In particular, the review should:
  - (a) examine the current roles, responsibilities and accountabilities of the Pharmaceutical Benefits Pricing Authority and the Pharmaceutical Benefits Branch, industry and other major stakeholders in respect of considering activities to achieve a listing
  - (b) develop new guidelines for the pPBAC processes for the consideration and negotiation of prices and other aspects for PBS listing purposes, to improve transparency and to streamline the timeframes and reduce the paperwork involved for all participants

- (c) the new guidelines should include principles for risk management arising from changes to the process, where appropriate.
- 3. The review should examine the recommendations in the context of the whole listing process and provide assurance that its recommendations will not introduce further complexity. It needs to ensure consistent and practical use of the information provided by the sponsors and by the PBAC and its sub committees to the process.
- 4. Determine whether, in light of any proposals for change, the organisation of resources and skills requirements across the system is appropriately aligned, and make any relevant recommendations.
- 5. Identify the high level/broad resource implications to government and industry for the options/recommendations of the review.
- 6. As a final step in the review, a reality test of the entire process will be undertaken, including consideration of risk to the industry and government.
- 7. Develop key performance measures and evaluation processes that determine the success of the implementation of the review's recommendations.

The review will be coordinated by an independent person who will be jointly appointed by the Department of Health and Ageing and Medicines Australia. A project team consisting of two representatives from each of the Department of Health and Ageing and Medicines Australia will provide input to the review. A senior level Reference Group, comprising one person from each of the Department of Health and Ageing and Medicines Australia will manage the review. One alternate will be appointed by each side to ensure that quick decision making can occur.

The review will report to the Minister for Health and Ageing within approximately four months from the start date of the review.