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Leader of the House of Representatives

Australia - United States Free Trade Agreement (AUSFTA)

&

the Pharmaceutical Benefits Scheme (PBS)

Statement on the Implementation of Australia's AUSFTA Commitments

February 2005

Introduction

The Free Trade Agreement signed by Australia and the United States (AUSFTA) in May 2004 included commitments relating to federal health care programs dealing with the reimbursement of prescription medicines. These were articulated in Annex 2C (Pharmaceuticals) to Chapter 2 - National Treatment and Market Access for Goods. In addition in an associated Exchange of Letters, Australia made a number of additional commitments to the United States.

Throughout the negotiation of the AUSFTA the Australian Government protected the fundamental architecture of the Pharmaceutical Benefits Scheme (PBS) and the integrity of the Pharmaceutical Benefits Advisory Committee (PBAC) as the pre-eminent advisory body to government on the listing of medicines on the PBS. The *National Health Act 1953* states that the Minister for Health and Ageing may only add to the PBS medicines recommended for listing by the PBAC. Consistent with this, no changes to the Act are necessary to implement Australia's AUSFTA commitments.

Following the conclusion of the FTA concerns were raised in Australia over the potential impact on the PBS of the commitment to establish an independent review of recommendations made to Government by PBAC. This was one of a range of measures agreed to enhance the transparency and accountability of the operation of the PBS.

The Government remains confident that the commitments it has made will have no adverse impact on the sustainability of the PBS. On the contrary, the independent review mechanism, together with other transparency measures agreed under the AUSFTA, will deliver improvements in the transparency of the PBS which will be of benefit to the pharmaceutical industry, prescribers, consumers and taxpayers.

In June 2004 I established a working group to advise on the three key issues that required detailed consideration before the scheduled entry into force of the AUSFTA on 1 January 2005. These were i) the design of the independent review mechanism for PBAC recommendations; ii) providing opportunities for hearings before PBAC and iii) improvements in transparency of PBS processes and outcomes. The working group comprised members of the Pharmaceutical Benefits Advisory Committee, including its consumer representative, Mr Mitch Messer, and representatives of Medicines Australia (MA).

In July I released a Public Consultation Document based on the interim advice from the working group. I would like to thank those individuals and professional bodies that responded to that Consultation Document. Those responses confirmed broad community and professional interest in greater transparency in the decision-making processes of the PBS and have been taken into account in this Statement.

The working group has now finalised its report and the following statement reflects input from the working group. I would like to put on record my gratitude to the members of the working group for their professional approach to the issues I asked them to consider and for the helpful and constructive advice they have offered. As recommended by the working group I will initiate a review of all relevant matters relating to the implementation of Australia's commitments under the AUSFTA within the first year of the operation of the new arrangements I have decided to implement.

1. Independent Review Mechanism

In the interests of greater transparency and accountability, Australia has agreed to establish a review mechanism that will be made available to an applicant when an application to have a drug added to the PBS has not resulted in a PBAC recommendation to list.

The relevant AUSFTA text is Annex 2-C which requires the Parties to:

> *… make available an independent review process that may be invoked at the request of an applicant directly affected by a recommendation or determination.*

This is clarified in the associated Exchange of Letters that states that:

> *Australia shall provide an opportunity for independent review of PBAC determinations, where an application has not resulted in a PBAC recommendation to list.*

It is proposed that the independent review mechanism should operate as set out below.

Guiding Principles

The independent review process will be independent of the applicant, the PBAC and of the staff of, or staff employed under contract to, the Department of Health and Ageing involved in any prior evaluations of the drug for the indication(s) requested.

An independent review may only be sought by an applicant – that is the sponsor of the application to the PBAC.

Independent review will only be made available where an application to the PBAC has not resulted in a recommendation to list.

A convenor will be appointed to manage the independent review function. The convenor will not conduct reviews but, for each review, will appoint a reviewer from a panel of identified experts.

The reviewer may seek clarification of the information available by discussion with the applicant or the PBAC or the Department, as arranged through the convenor. Following consultation with the convenor the reviewer may also consult, as appropriate, with other relevant experts.

Any consultations relating to the conduct of the independent review will be conducted in closed session.

The outcomes of the independent review will be made publicly available in a similar timeframe to the publication of outcomes from PBAC meetings.

The timeline for the conduct of the independent review will be such that it involves no additional delay in the PBS processes. There will be no time incentive, or disincentive, for applicants to seek a review in preference to making a resubmission to the PBAC.

The findings of the independent review will be reported to the PBAC.

After consideration by the PBAC, the review findings and the outcome of the PBAC's reconsideration of the submission in light of the findings of the review will be reported to the Minister for Health and Ageing within 15 days of the PBAC's consideration.

Applicants will retain the option to resubmit to the PBAC if additional data or information subsequently become available, but a resubmission will not be accepted while a review is in process.

Operation of the Independent Review

Management of the independent review process will be undertaken by a convenor. The convenor's role will be to ensure the integrity and efficient operation of the review process.

Individual reviews will be conducted by a reviewer, selected from a panel of experts in relevant disciplines including, but not limited to, clinical pharmacology, epidemiology, pharmacoepidemiology, health economics, biostatistics, and internal medicine subspecialties.

The applicant seeking a review will identify those issues that are in dispute and the review will focus on these issues. The issues must reflect the PBAC's reasons for not recommending listing. The convenor will consider the issues in dispute in appointing an appropriate reviewer. The reviewer must not be an employee or member of the evaluation group that undertook the initial evaluation of the application to the PBAC.

The reviewer will be an individual whose qualifications and expertise are relevant to the key issue(s) under review.

When there are disparate issues in contention, the reviewer may seek advice as required after consultation with the convenor. Any person consulted would be identified in the reviewer's report. The reviewer and all people consulted during a review will be required to lodge conflict of interest statements with the convenor.

The review will have access to all the information placed before the PBAC by the applicant, as well as details of the recommendations of the PBAC together with the reports to the PBAC of its sub-committees on the application. No new information is to be provided to the reviewer.

Conduct of the review

The applicant will put a request for a review to the convenor in writing, and provide a statement outlining the issues about which the review is sought.

The convenor will notify the applicant and the PBAC of the name of the reviewer selected to conduct the review.

The appointed reviewer must declare to the convenor any real or potential conflicts of interest. The convenor will ensure that the reviewer has the credentials to be fair and impartial in conducting the review.

The reviewer shall take into consideration all available documents, information and other written material available to the PBAC, including documents, information and material relating to the issues in dispute and to arguments and submissions upon the matters under consideration. However no new information will be considered, beyond that previously made available to the PBAC.

A review will be completed in a timeframe that allows the reporting back to the PBAC meeting in the same timeframe as a resubmission.

The convenor will lodge the reviewer's report to the PBAC with the PBAC secretariat no later than 4 weeks before the PBAC meeting at which the matter will be considered, and at the same time provide copies to the applicant.

The applicant will be invited by the PBAC Secretariat to provide a pre-PBAC response to the reviewer's report.

Confidential information will be afforded the same level of protection as information put to the PBAC.

Management of reviews

Criteria for selection of convenor

The following criteria are proposed for the selection of the convenor of the independent review mechanism:

- Substantial experience at a senior level in industry, commerce, public administration, academe, a profession or the public service;
- Knowledge of public administration together with experience in health care matters;
- Demonstrated commitment to impartiality and objectivity and evidence of standing and respect within the community;
- Free of actual or perceived conflicts of interest;
- Strong communication skills.

Duties and responsibilities of the convenor

The following duties and responsibilities will be carried out by the convenor of the independent review mechanism:

- Management of the review process including liaison with the parties and maintenance of its independence;
- Establishment and maintenance of a panel of experts;
- Facilitation of selection and appointment of experts for particular reviews;
- Oversight and implementation of rules and procedures relating to reviews;
- Monitoring outcomes, adherence to rules, procedures and ethical standards;
- Periodic (annual) reporting on review of the process to the Government.

It will be the responsibility of the convenor to ensure, at the time of selecting a reviewer of an application, that the nominee does not have a real or perceived conflict of interest.

Criteria for selection of expert panel members

The single mandatory criterion for selection of expert panel members is recognised expertise in a relevant discipline. Relevant disciplines include:

- Clinical pharmacology

- Epidemiology
- Pharmacoepidemiology
- Health economics
- Biostatistics
- Internal medicine subspecialties

Review Outcomes

Publication of the outcomes of the independent review will be guided by the same principles for publication as are outlined in Section 4 (Transparency Principles). The following documents will be made public:

- the Public Summary Document (PSD – see Section 4) reflecting the PBAC's consideration of the application in question;
- the sponsor's reasons for seeking a review (in the form of the "sponsor comments" section in the PSD);
- the report of the Independent Reviewer;
- the sponsor's response to the Independent Review;
- the outcome of the PBAC's reconsideration of the application in question (as a PSD);

The content of the report from the Independent Reviewer, and the timing of its release, cannot be determined until a Convenor is appointed.

2. Hearings before PBAC

Under the AUSFTA Australia agreed to provide enhanced transparency to ensure meaningful consultation and accountability in PBS processes. The relevant provisions of the AUSFTA Side Letter include the undertaking that:

> *In order to ensure transparency, … Australia shall provide … the opportunity for a hearing before the PBAC while it is considering reports or advice from the technical subcommittees to the PBAC regarding its application.*

The process currently allows for a number of "contact points" between the sponsor companies and the PBAC process. For example:

- Pre-submission (verbal) – meetings with staff of the Department of Health and Ageing;
- Provision of written responses to Departmental reports;
- Provision of written responses to PBAC sub-committee reports – an innovation reflecting the newly created 17-week PBAC cycle of meetings;
- Following a recommendation not to list, discussion with Departmental staff and the PBAC Chair to facilitate re-submission.

In order to meet Australia's undertaking to afford opportunities for hearings before the PBAC, while at the same time avoiding the process becoming unworkable.

- Hearings before the PBAC will be confined to specific issues and limited in scope, duration and frequency;

- Medicines Australia will develop a code of practice to guide applicants in the most appropriate circumstances for seeking a hearing;

In view of the need for a pragmatic implementation of this recommendation in the Free Trade Agreement, the PBAC and Medicines Australia will, by mid-2005, consider the alternative option of a hearing before the sub-committees of the PBAC.

3. Transparency Principles

Consistent with National Medicines Policy, which states that consumers and health practitioners should be encouraged to understand the costs, benefits and risks of medicines, the working group acknowledges that all stakeholders in the PBS have a need to be informed about PBAC recommendations.

Limited information is currently published on the Department of Health and Ageing website, providing only the outcome of each application and a brief summary of the PBAC's reasons.

The following approach will now therefore apply to the transparency of information:

- Details of PBAC recommendations will be available to the public in a timely manner following each PBAC meeting;
- A Public Summary Document (PSD) will be generated to provide to the public information pertaining to PBAC recommendations;
- The information will include sufficient relevant clinical, economic and utilisation data to enable stakeholders to understand submissions to the PBAC and the PBAC's view of those submissions;

The PSD will provide information on all aspects of PBAC recommendations, where relevant covering the following:

1. Purpose of the submission – request made to the PBAC
2. Background
3. Registration status
4. Listing requested and PBAC's view
5. Clinical place for the proposed therapy
6. Comparator
7. Clinical trials
8. Results of trials
9. Clinical claim
10. Economic analysis
11. Estimated PBS usage and financial implications
12. Recommendation and reasons
13. Context for decision
14. Sponsor's comments

The information contained in the PSD will be consistent with that included in the PBAC minutes pertaining to a particular recommendation. In consultation the PBAC and the

sponsor will prepare a draft of the PSD which will be reviewed by both parties taking into account the Commonwealth's duty of confidence to sponsors, where such a duty exists. Both parties will work cooperatively and constructively and negotiate in good faith to provide a PSD which meets the needs of all stakeholders.

Where circumstances warrant the disclosure of information for which the Commonwealth has a duty of confidence, the PBAC and the sponsor will negotiate in good faith to seek a solution which, while protecting confidential information, will enable stakeholders to have adequate information to understand PBAC recommendations.

A sponsor may provide on its website comments additional to those contained in the PSD. Any information or opinion which is published, including that in the PSD should be balanced, fair, and avoid subjectivity/bias.

Specific issues relating to content, associated with proposals from sponsors for listing of drugs that are not recommended for listing after a first consideration by the PBAC, will be taken into account in developing the PSD. Further, a delay in the release of a PSD for those drugs, beyond the cut-off date for the following PBAC meeting, will be considered by the PBAC with a view to minimising any adverse impact on those sponsors. If, however, a sponsor of an application which is not recommended for listing after a first consideration by the PBAC seeks an independent review of that recommendation, a PSD will be made available prior to the commencement of the review process.

A Standard Operating Procedure (SOP) will be developed to cover the preparation of the PSD. The Agreed Guiding Principles for Publication of PBAC Recommendations annexed to the working group report will also guide the preparation of the PSD.

To facilitate its implementation the release of PSDs will be phased in during the first half of 2005. Companies seeking an independent review as a result of outcomes from the PBAC's March meeting will be required to have the relevant PSD published.

The PBAC will convene a consultation forum with sponsors early in 2005.

The parties (PBAC and sponsors) will monitor the phasing in of the PSD with a view to advising on the need, or otherwise, of a mechanism for resolving disputes between the PBAC and sponsors in regard to the content of a PSD.

12-Month Review

Twelve months after the implementation of these processes a review will be undertaken to ensure that the provisions set out in the text of the FTA, as well as the objectives of accountability and transparency for all stakeholders, are being met.