The Hon Tanya Plibersek MP
Minister for Health

RESPONSE TO THE RECOMMENDATIONS OF THE COMMUNITY AFFAIRS REFERENCES COMMITTEE REPORT ON CONSUMER ACCESS TO PHARMACEUTICAL BENEFITS

RECOMMENDATION 1
The committee recommends that the government examine ways in which there can be greater engagement with consumers in decisions to create new therapeutic groups, particularly when considering the potential impacts new therapeutic groups may have on consumers.

Response
The Government supports the recommendation and is currently looking at new ways to enhance the consumer input in Pharmaceutical Benefits Advisory Committee (PBAC) matters.

An important development that occurred during the course of the inquiry was the signing of a Memorandum of Understanding (MoU) between the Commonwealth and Medicines Australia, with effect until 30 June 2014. Under the terms of the MoU (Clause 16), the Government has undertaken not to create any new therapeutic groups over the period of the agreement with two exceptions:

- The three Therapeutic Groups which were announced in the 2009 Mid-Year Economic and Fiscal Outlook and comprising drugs for the treatment of depression, osteoporosis and Paget disease;
- A minor variation or a different sponsor of an already listed drug and where the PBAC advises that it is interchangeable on an individual patient basis with members of the extant Therapeutic Group.

The Therapeutic Group Premium (TGP) pricing policy has been in place for 13 years and represents an extension of the evidence-based assessment of cost-effectiveness that is required by legislation for subsidy on the Pharmaceutical Benefits Scheme (PBS). It ensures that the Government does not pay extra unless there is evidence of extra benefit.

As of the August 2011 *Schedule of Pharmaceutical Benefits* there are only seven drug products that attract a therapeutic group premium (five for hypertension and two for ulcers) out of over 3,900 on the PBS. In the therapeutic areas of cardiology and gastroenterology where medicines with therapeutic group premiums exist, there are multiple alternatives with no premium and options for exemption for those patients who cannot take another drug on clinical grounds.

The Senate committee acknowledged the work undertaken by the Government to educate and inform consumers and prescribers at the time the therapeutic group policy was introduced and

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still operate to explain the therapeutic groups currently available, together with the alternatives and the process for seeking exemptions from a therapeutic group premium on behalf of a patient. The community pharmacy network is an important source of information on PBS medicines with either a brand or a therapeutic group premium while the PBS information line (1800 020 613) is also available to assist consumers in this area.

Health consumers have a unique and important perspective on health services as the users and beneficiaries of health care and ultimately those who pay for it. The Government is currently looking at new ways to enhance the consumer input in PBAC matters, such as:

- greater consumer participation in the organisation and conduct of the Joint Medicines Policy Conference co-hosted by the Department of Health and Ageing and Medicines Australia. This conference, organised every two years, is pivotal in facilitating discussion on the varying perspectives on how public subsidy of medicines operates in Australia, with a particular emphasis on the assessment of medicines through the PBAC; and
- in-depth consultation with the Consumers Health Forum to redesign the public comments pages on the Department's web-site to facilitate more meaningful consumer input to PBAC agenda items, which are available to the Committee during its considerations.

Both the Government and the PBAC have a long history of improving such input from patients and from the general community. The PBAC has a consumer representative as a full member of the committee; comments are sought from the general public on subsidy applications on the PBAC agenda and these are provided to the PBAC when the submissions are considered; and the PBAC may request a formal consumer impact statement from the Consumers Health Forum when considering the impact of a health condition and the possible improvement in the quality of life for people using the proposed treatment.

Although no new therapeutic groups will be created over the period of the MoU except in specific and limited circumstances, the Government in the development of any future therapeutic groups will endeavour to engage consumers in meaningful consultation, as appropriate within the Budget context. Therapeutic groups remain a valuable pricing policy to reduce costs to the PBS. The policy reflects a 13 year long view of successive governments that PBS patients and taxpayers should pay comparable prices for similar health outcomes.

RECOMMENDATION 2
The committee recommends that the Pharmaceutical Benefits Advisory Committee:
• develop agreed principles of what constitutes "interchangeable on an individual patient basis";
• develop criteria by which the "interchangeability" of a medicine will be determined; and
• publish both the agreed principles and criteria.

Response
The Government supports the recommendation in principle. We consider that transparency in decision making is important, but note that the current processes are appropriate.

The Government and the PBAC have a long history of improving consumer input from patients and the general community via various avenues and in providing information about PBAC recommendations. Information about therapeutic groups is available on the Department of Health and Ageing's website at www.pbs.gov.au/browse/therapeutic-group ; while information about PBAC recommendations, in the form of public summary documents, are available at http://www.health.gov.au/internet/main/publishing.nsf/Content/public-summary-documents-by-product

As required under the *National Health Act 1953* (the Act), the PBAC gives clear advice to the Minister to the effect that a drug or medicinal preparation should, or should not, be treated as interchangeable on an individual patient basis with another drug or medicinal preparation.

Further this matter has been the subject of a Federal Court case that considered the validity of the PBS Statins – Higher Potency (HP) therapeutic group comprising the drugs rosuvastatin (Crestor®) manufactured by AstraZeneca Pty Ltd and atorvastatin (Lipitor®) manufactured by Pfizer Australia Pty Ltd. This matter was brought by AstraZeneca against the Minister of Health and Ageing and members of the PBAC. The hearing on this matter was held in Sydney before Justice Buchanan on Friday 25 March. 2011

In his decision, delivered on 12 May 2011, Justice Buchanan found that the PBAC had performed its functions in accordance with the Act, in providing advice that atorvastatin and rosuvastatin should be treated as interchangeable on an individual patient basis. His Honour found that neither the PBAC, nor the Minister, are required to consider the individual dosages of the medicine when assessing interchangeability for the purposes of forming therapeutic groups under the Act. This means the Statins-HP therapeutic group was validly constituted and savings from the creation of the therapeutic group will continue.

This court decision has confirmed the Government's position that consideration of interchangeability at the drug level, and not at the form and strength level, is consistent with the Act. In light of this decision, it was considered that the existing information and processes are adequate and that publication of further definitions is not required.

RECOMMENDATION 3
The committee recommends that the Department of Health and Ageing provide regular and ongoing education and information to prescribers to ensure they are aware of the exemptions from payment of a brand premium and the process for seeking those exemptions on behalf of a patient.

Response
The Government supports the recommendation in principle.

There was some concern expressed during the inquiry that not all doctors may be aware that they are able to seek an exemption from a therapeutic group premium on behalf of their patients.

However the number of drug products on the PBS with a therapeutic group premium, and hence the option to apply for an exemption for an individual patient, is very low. As of the August 2011 *Schedule of Pharmaceutical Benefits*, therapeutic group premiums apply to only 7 out of over 3,900 drug products and are in the field of gastrointestinal medicine and cardiology. Some prescribers outside of these fields may be unfamiliar with the process for seeking exemption to a TGP, however we do not consider the concerns expressed by the clinicians appearing before the committee are representative of clinicians working in those fields where Therapeutic Group Premium (TGP) drugs are prescribed.

All prescribers have ongoing access through the *Schedule of Pharmaceutical Benefits* and their computer dispensing software to the specified clinical criteria by which they may apply for exemption from a therapeutic group premium for their patient. The process by which this happens is the same one prescribers already use to apply for approval from Medicare Australia to prescribe certain restricted drugs on the PBS. The *Schedule of Pharmaceutical Benefits*, in both in hard-copy and web-based versions, also contains a separate, regularly updated TGP policy section featuring the PBS items that still attract a therapeutic group premium and the process whereby individual patient exemptions may be sought. The Government will continue to use these mechanisms to ensure prescribers are informed about TGPs.

RECOMMENDATION 4

The committee recommends that:

• the threshold for Cabinet consideration of high cost medicines be adjusted, initially to the value the threshold would have had, had it been indexed annually since 2001;

• subsequently, the threshold should be indexed annually; and

• the Department of Health and Ageing examine the most appropriate indicator for indexing the threshold.

Response

This recommendation will be considered in conjunction with the Government's response to the recommendations of the Finance and Public Administration References Committee in its report on the Government's administration of the Pharmaceutical Benefits Scheme presented on 17 August 2011.