Consumers Health Forum of Australia

# Submission to the Senate Finance and Public Administration References Committee Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme

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## *Introduction*

The Consumers Health Forum of Australia (CHF) welcomes the opportunity to provide input into the Senate Finance and Public Administration Committee Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme (PBS).

CHF is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF members and stakeholders have a strong interest in issues related to access to medicines through the PBS. Recent changes to the process for listing medicines on the PBS have created an enormous level of concern among health consumer organisations, resulting in an unprecedented joint campaign by sixty health consumer organisations to oppose these changes.

This Submission outlines the background to the PBS listing process, the recent changes from February 2011, key consumer concerns and conclusion. Comments in this submission relate to items (a), (b) and (d) to (g) of the Inquiry's Terms of Reference.

## *Background*

### *The PBS Listing Process: Until February 2011*

New drugs seeking Government approval are assessed for relative clinical necessity and cost-effectiveness by the Pharmaceutical Benefits Advisory Committee (PBAC), a government-appointed advisory body comprised of clinical and economic experts, as well as consumer expertise. Drugs that are deemed by PBAC to demonstrate cost-effectiveness and meet a clinical need in the Australian community are recommended to the Minister for Health and Ageing for listing on the PBS.

Until February 2011, drugs that had been recommended by the PBAC were almost invariably approved for listing on the PBS. Cabinet consideration was required for the listing of any drugs with a predicted financial impact of more than $10 million per year in any of the first four full years of PBS listing, but was not required for drugs whose predicted financial impact fell below this threshold.

The PBAC process is well-understood by industry, and is considered to be transparent and independent. Information about the PBAC processes and what kind of evidence is taken into account is readily available.[1] There are mechanisms for consumer input to PBAC processes to ensure that their perspective is considered.

### *The PBS Listing Process: After February 2011*

In February 2011, citing financial reasons, Cabinet deferred approval for listing of seven new medicines and a vaccine on the PBS, in spite of positive recommendations from the PBAC for their inclusion. These medicines had been evaluated by the PBAC as providing value for money to taxpayers as well as meeting a clinical need for consumers.

In conjunction with the decision to defer listing of medicines, the Government decided, without consultation, that all drugs pending approval for the PBS will be required to be reviewed by Cabinet, even after a positive recommendation from the PBAC. This is a substantial change from the previous arrangement that only drugs with a financial impact of over $10 million per year in any of the first four years of PBS listing had to be considered by Cabinet.

The only explanation provided for these changes is the need to get the Budget back into surplus.

Some of the deferred drugs have since been added to the PBS. However, others remain in limbo. It is unclear on what basis or upon which criteria the Cabinet has made the decision to list some drugs and not others. This is the key concern of many consumers – that the decisions made by Cabinet to arbitrarily defer listing of some drugs and not others politicises what has been a process of relative integrity for decades until February 2011.

Consumer concerns about the new process are outlined below.

### *Key Issues*

### *Consumer Concerns about the Changed PBS Listing Process*

CHF has seen an unprecedented level of consumer concern about these changes, demonstrated by an enormous volume of telephone calls and written correspondence to CHF and captured in responses to an online survey undertaken in March/April 2011. A report on the survey outcomes is at Attachment A.[2]

The level of consumer concern is further demonstrated by the endorsement by sixty health consumer organisations of a Statement of Public Intent condemning the changes to the PBS listing process and calling on the Federal Government to reverse the decision. The statement is at Attachment B.[3] A list of endorsing health consumer organisations is at Attachment C.

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[1] See http://www.pbs.gov.au/info/industry/listing/participants/pbac

[2] The survey report can also be downloaded at https://www.chf.org.au/files/Survey-report-complete-.pdf

[3] The statement can also be downloaded at https://www.chf.org.au/files/Poster.pdf

Consumer concerns about the changes to the PBS listing process can be broadly summarised as follows:

1. Delays in access to essential medicines
2. Lack of transparency in the new process
3. Politicisation of PBS listing process
4. Lack of consideration of other healthcare costs likely to arise as a result of consumers not having access to essential medicines.

Each of these is explored in more detail below.

**1. Delays in access to essential medicines**

A significant concern for consumers is that they will face further delays in affordable access to essential medicines as a result of the changed process. As noted above, the listing of seven medicines and a vaccine was deferred in February this year. The vaccine and two of the drugs have since been made available through the National Immunisation Program and the PBS, but five remain unapproved. Consumers who need access to these medicines face indefinite delays before these drugs will be made available to them. There has been no indication from Government when, or if, the deferral decision for the remaining drugs will be reviewed.

Concerns about delays do not only relate to those drugs which have already been deferred. Consumers now face even greater uncertainty about when they will have access to the latest, most effective medications, as even after a positive PBAC recommendation there is a risk that Cabinet will again decide to defer listing of some drugs. The lack of transparency around the Cabinet decision-making process is a further concern; this is discussed in more detail below.

Delays are also likely to arise as a result of Cabinet consideration of *every* new medicine, instead of only those with a financial impact of more than $10 million per year. Cabinet already deals with a substantial agenda. Consumers are concerned that adding consideration of every single positive PBAC recommendation to that agenda will create an unmanageable workload with inevitable ‘log-jams’ in approvals – creating further delays.

**2. Lack of transparency in the new process**

As noted above, the PBAC process is well-understood and well-respected, and viewed as transparent and independent. Sponsors of new drugs have a good understanding of the evidence used in decision-making processes, and consumers have the opportunity to provide input to the process.

These are all elements that are missing from the new listing process. Consumers are concerned that there is now a lack of transparency about the criteria against which drug listings are being assessed. It is unclear if Cabinet is drawing on any additional evidence apart from that considered by the PBAC, and what expertise is available to assist Cabinet to make its decisions.

While the criteria used in the PBAC process are clear and are outlined in the relevant legislation, it appears that there are no formal criteria, and certainly no public criteria, used in the Cabinet process. In Senate Estimates on 31 May 2011, the Secretary of the Department of Health and Ageing, Ms Jane Halton PSM, was asked if Cabinet considered the same criteria as the PBAC, or if there were other formal criteria that they considered in their assessment. Her response was:

> *The answer to that is, are there formal criteria, no; is there an explanation for the ones that were chosen, yes, but in terms of a formal criteria, no.*[4]

The lack of any publicly available, formal criteria means that there is also no transparency around what evidence is considered by Cabinet when it is making its decision about what drugs should be available at an affordable price to Australian consumers. It could be that it is the same evidence that is considered by the PBAC, but there might be other, unknown factors that are taken into consideration. There is also no transparency around whether Cabinet seeks any further expert advice on the listing of these drugs. Consumers are concerned that Cabinet members do not have the necessary expertise to assess whether drugs are clinically necessary and provide value for money, while the members of the PBAC do have this expertise. As one respondent to CHF's survey argued:

> *Who is the expert on the subject - a group with training, knowledge and experience with input from consumers OR Cabinet? I was under the illusion that Cabinet was guided by experts in the field – otherwise why go through the sham of "consultation"?*[5]

Consumers have argued strongly that the PBAC process is very rigorous and already considers cost-effectiveness in addition to clinical effectiveness and clinical need. They are concerned that Cabinet is disregarding the advice that it has received, reducing the integrity and worth of the PBAC.

In addition to raising concerns among consumers, the lack of transparency in the new process creates uncertainty for pharmaceutical companies, which could impact consumer access to medicines. Consumers have expressed concern that removal of transparency from the listing process will result in pharmaceutical companies not wanting to risk potential deferral of their products, and therefore not applying to have their new products listed on the PBS. This could mean that drugs will simply not be available to Australian consumers.

## 3. Politicisation of PBS listing process

The lack of transparency in the new process has also created consumer concern that the process has become politicised. Consumers are concerned that, without any clear criteria for assessment, the listing process will become open to political whims and external interference.

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[4] Commonwealth of Australia, *Proof Committee Hansard: Senate Community Affairs Legislation Committee*, 31 May 2011, p93 (Ms Jane Halton, Secretary, Department of Health and Ageing)
[5] CHF 2011 *Keep your Cabinet out of our medicines! Results of a consumer survey on changes to the PBS listing process*, CHF, Canberra.

Consumers do not want a situation in which drugs are listed on the PBS to win votes or boost opinion polls. They also do not want to see a process which allows those consumer organisations with the loudest voice or the most media and political connections to lobby for their drug to be listed, while less well-resourced groups supporting people with less 'marketable' illnesses must continue to wait indefinitely for their essential medications.

Similarly, it is likely that pharmaceutical companies seeking listing will need to undertake rigorous lobbying of Cabinet members to achieve a positive outcome.

**4. Lack of consideration of other healthcare costs likely to arise as a result of consumers not having access to essential medicines**

Consumers have rejected the argument from Government that it is necessary to defer some medicines in order to bring the Budget back into surplus. Apart from the fact that the PBAC already considers whether these medicines are cost-effective, consumers have argued that there are considerable savings to be made across the Budget if people have access to the right medications.

If consumers are receiving treatment that meets their needs and is effective for them, they are less likely to require hospitalisation and less likely to require frequent visits to a GP or other health professionals. CHF argues that these are savings that the Government must take into consideration. Further, the savings are not limited to the health budget. If consumers are receiving effective treatment, they are more likely to be able to participate more fully in society – including in the workforce – meaning that they are contributing to national productivity and paying taxes, rather than having to draw on Government benefits.

Consumers have argued that these savings must be considered if the Government is to use the Budget as an excuse for deferring essential medicines.

## *Conclusion*

CHF has seen an unprecedented level of concern about the changes to the PBS listing process and resulting delays.

While it may be necessary to minimise PBS costs, CHF argues that allowing Cabinet to be the final arbiter of which medicines should be available to Australians is not the solution. Governments over many years have worked with the Department of Health and Ageing to identify strategies to minimise PBS costs without reducing consumer access to essential medicines; recent examples include the introduction of therapeutic groups, as well as the Memorandum of Understanding between the Government and Medicines Australia with its stronger price disclosure requirements and subsequent reductions in the price paid by Government for generic medications. There is also the potential to find savings elsewhere in the health budget and CHF would welcome the opportunity to identify possible options. CHF calls for alternative solutions to be found to minimise PBS costs *without* introducing politicisation of the listing process.

At the very least, we seek a higher level of transparency around what criteria, evidence and expertise Cabinet is using to make their decisions about the availability of medicines in Australia.

Ultimately, however, we call on the Committee to seek the reversal of this short-sighted decision by the Government, and return to the process that has worked well and supported consumer access to the best available medicines for over 50 years.

As 60 health consumer organisations have argued, Australia can afford these medicines now. People with chronic illnesses should not have to suffer continued delays in access to medicines because of the Government's very short term budgetary goals.

Consumers Health Forum of Australia

The Consumers Health Forum of Australia (CHF) is the national peak body representing the interests of Australian healthcare consumers. CHF works to achieve safe, quality, timely healthcare for all Australians, supported by accessible health information and systems.

CHF does this by:

1. advocating for appropriate and equitable healthcare
2. undertaking consumer-based research and developing a strong consumer knowledge base
3. identifying key issues in safety and quality of health services for consumers
4. raising the health literacy of consumers, health professionals and stakeholders
5. providing a strong national voice for health consumers and supporting consumer participation in health policy and program decision making

*CHF values:*

- our members' knowledge, experience and involvement
- development of an integrated healthcare system that values the consumer experience
- prevention and early intervention
- collaborative integrated healthcare
- working in partnership

CHF member organisations reach millions of Australian health consumers across a wide range of health interests and health system experiences. CHF policy is developed through consultation with members, ensuring that CHF maintains a broad, representative, health consumer perspective.

CHF is committed to being an active advocate in the ongoing development of Australian health policy and practice.