Consumers
Health Forum
of Australia

Submission to the Senate Community Affairs References Committee Inquiry into Consumer Access to Pharmaceutical Benefits

31 March 2010

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Introduction

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 welcomes the opportunity to provide comment to the Community Affairs References Committee Inquiry into Consumer Access to Pharmaceutical Benefits.

This brief submission is based on the views of consumers who responded to our request for input into this submission. It aims to provide the Senate Community Affairs References Committee with key comments from CHF members on the PBS reform. To inform its submission, CHF called for input from its members on:

1. the seven identified areas of the Inquiry, and
2. general comments on the PBS reform.

This submission identifies some key issues that have impacted consumers as a result of the reform and areas that have raised concern amongst consumers, and concludes with some overall recommendations in areas where consumers consider further development and consideration would be beneficial.

Key issues

Consumers must not be disadvantaged

In assessing any health reform, it is imperative to assess the impact on consumers, including access, cost, safety and quality. When the PBS reform was announced in November 2006, the Minister for Health and Ageing stated that consumers would not be disadvantaged by the reform (Department of Health and Ageing [DoHA], 2010, p18). As discussed in more detail below, CHF has not received any indication from its members that they have been disadvantaged by PBS reform. However, it is important that the impact on consumers continues to be monitored, and that consumers are involved in ongoing decision-making.

Improved affordability of PBS drugs is welcomed

CHF welcomes the benefits for consumers of increased affordability of medications that have resulted from the PBS reforms. According to DoHA's report *The impact of PBS reform: report to parliament on the National Health Amendment (pharmaceutical benefits scheme) ACT 2007*, the objective of PBS reform is to "achieve better value for money and drugs that are subject to price competition" (DoHA, 2010, p2). DoHA found that the reforms have had a significant overall positive impact on the affordability of PBS drugs for most consumers.

DoHA also reported that the introduction of the premium free dispensing incentive, which encouraged pharmacies to dispense brands of substitutable PBS medicines that were available for the co-payment with no brand premium, has seen an overall higher level of premium free dispensing since the changes in August 2008, resulting in a reduction in cost to consumers (DoHA, 2010, p4).

New therapeutic groups should not reduce access to necessary medicines

Consumers acknowledged that new therapeutic groups should not reduce access to necessary medicines, including high cost medicines for consumers, as there is always more than one drug in a therapeutic group. If one drug is withdrawn by a company because it does not want to reduce the price of its product in line with other products in the therapeutic group, other drugs within the therapeutic group will still be available for use.

PSB reform should not reduce community access to medicines

CHF has not received any reports from its members of reduced community access to medicines since the introduction of the PBS reforms, and according to DoHA, the reforms do not to appear to have impacted negatively on community access to medicines.

Broader community consultation would enhance PBS processes

CHF considers that broader community consultation would enhance PBS processes. One mechanism to achieve this would be direct involvement of consumers in the Access to Medicines Working Group (AMWG).

Clinical effectiveness must be the most important consideration

Consumers argued strongly that clinical effectiveness must be the most important consideration when assessing evidence for inclusion of a medicine on the PBS or for the interchangeability or equivalence of medicines. Some consumers have expressed concerns, outlined in more detail below, about the evidence base for PBS approvals and therapeutic groups.

Therapeutic groups should increase access

Consumers identified that medicines that were not accessible for certain types of diseases or illnesses might become accessible in a new therapeutic group, which would benefit consumers with that particular disease or illness.

Regulators and consumers should critically appraise the evidence and the benefit to consumers before establishing new therapeutic groupings

Consumers also urged caution in increasing accessibility for certain drugs, with one consumer providing the following example:

> *Recently, the Food and Drug Administration (FDA) has indicated the possibility of expanding the use of statins and other cardiovascular medicines to aid*

prevention of cardiovascular disease rather than just treating it. This shift would move to the prescribing of these medicines for consumers at a younger age (e.g. from 60 years of age on average down to 50 years or even less).

While this could lead to the creation of a new 'preventative medicine' therapeutic group, it is important that regulators and consumers critically appraise the evidence and the benefit to consumers before establishing new therapeutic groupings which might increase the availability of particular medications.

Therapeutic groupings should be based on scientific advances, not commercial imperatives

Transparency around therapeutic groupings and public information about how and why these groups are established is essential. Concern was expressed by some consumers about whether the establishment of new therapeutic groupings is based on scientific advances or commercial imperatives.

Regulatory scrutiny of clinical evidence is imperative

Consumers argued that it is important that there is close, impartial scrutiny of the clinical evidence before high cost drugs are approved. Some consumers considered that new therapeutic groups, such as biological medicines, still lack strong clinical evidence, and are generally high in cost. Regulatory scrutiny of clinical evidence is imperative to protect the safety of consumers and their interests as funders of the health system.

Clinical evidence for interchangeability or equivalence must be the basis for drug approvals

Consumers expressed concern that not all decisions are based on clinical effectiveness, and argued for improved transparency around drug approvals.

Some consumers who provided comments to CHF argued that the clinical evidence used to qualify drugs as interchangeable or equivalent can sometimes be poor. For example, in a Pharmaceutical Benefits Advisory Committee (PBAC) report in 2008, a new formulation of a cancer chemotherapy drug (albumin-bound paclitaxel) was rejected for listing on the PBS because it was not as clinically effective as the original formulation of the drug (paclitaxel). Following another submission by the company based on cost-effectiveness, the drug was approved for listing on the PBS. Consumers expressed concern that the clinical effectiveness of the new formulation of the drug had not been proven, yet it had been approved by PBAC, apparently for financial reasons.

Consumers must be consulted in the development of new therapeutic groups

It appears that there is no public consultation in the development of new therapeutic groups. Consultation is undertaken by PBAC, which informs the companies affected that they are considering the development of a new therapeutic group and seeks the relevant information directly to assist them in the decision making process. Companies are given an opportunity to provide information about why their product should not be included in the group. However, consumers are not currently consulted.

Greater transparency will generate public confidence

Consumers would like to see greater transparency in the process and timing of consideration of high cost drugs by Cabinet. For example, if a medicine is being pushed through Cabinet ahead of other medicines or in a tighter time frame, increased transparency would provide consumers a better understanding of why one medicine has been given priority, creating greater confidence in the process. It would also provide an opportunity for greater external scrutiny of whether there is sufficient evidence for the clinical effectiveness of these medicines. Greater transparency will also ensure that Cabinet's decisions on medicines approvals are not influenced by pharmaceutical companies' marketing, something about which consumers are sceptical.

Clinical effectiveness must be the basis of Cabinet approvals

The clinical effectiveness of the medicine needs to be the first and most important consideration in the decision making process. While it is important that approval of high cost medicines should be considered in a timely manner, accelerating the process may not be useful if the evidence is scarce. It is important that adequate evidence is provided to enable Cabinet to make an informed decision that protects consumers' safety. The establishment of clear guidelines that identify the minimum evidence level for a medicine to be approved would be a positive step in establishing timeframes and legitimacy for decision making.

There should be identified timeframes for Cabinet approvals

Consumers suggested setting a clear timeframe for consideration of medicines approvals by Cabinet. This was viewed as important because these decisions must fit in with other items on the Cabinet agenda, and potentially risk being delayed due to other priorities.

Recommendations

That there be broader community consultation to enhance PBS processes, including at least one consumer representative appointed to the AMWG.

That clear guidelines be established and widely publicised identifying a minimum level of clinical evidence, proving the clinical effectiveness of a drug for listing on the PBS for Australian consumers.

That clinical effectiveness be the most important criterion when establishing therapeutic groups and assessing evidence for drug interchangeability or equivalence.

That in the establishment of new therapeutic groups:

- Regulators and consumers critically appraise the evidence and the benefit to consumers before establishing new therapeutic groupings
- Decisions should be made based on scientific advances, not commercial imperatives
- Consumer consultation is undertaken in the development of new therapeutic groups
- There be transparency around therapeutic groupings, providing public information about how, and why, these groups are established.

That increases to subsidies should be considered as evidence becomes available proving the effectiveness of new therapeutic groups, taking into account the level of consumer need and health impact.

That there be close, impartial scrutiny of the clinical evidence before high cost drugs are approved.

That there be greater transparency in the process and timing of consideration of high cost drugs by Cabinet.

Conclusion

Consumers are the users and beneficiaries of medicines, and are also ultimately the funders of the PBS. CHF welcomes the Inquiry into Consumer Access to Pharmaceutical Benefits and appreciates the opportunity to provide comment.

PBS reform has bought with it both cost savings and greater access to PBS listed medicines to consumers. However, consumers have identified a range of areas in which greater transparency and consumer involvement would be beneficial.

Most importantly, consumers want clinical effectiveness to guide decision making about which therapeutic groups are formed and about medicine interchangeability or effectiveness. The level of subsidy provided and which high cost drugs are approved should also be driven by this imperative.

We look forward to the outcomes of the review and future developments of PBS Reform.

References

Department of Health and Ageing. (2010). *The impact of PBS reform: report to parliament on the National Health Amendment (pharmaceutical benefits scheme) ACT 2007* (Pub. no. 6312). Canberra, Australia: DoHA.

Mann, D. (2009, December). FDA considering statin use for those with normal cholesterol. *Health.com.* Retrieved from http://www.health.com/health/condition-article/.

Representing consumers on national health issues

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 thousands 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.