Submission to Senate Finance and Public Administration Committees enquiry into the Government's administration of the Pharmaceutical Benefits Scheme.

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I make this submission as a private citizen and as an active member of the organised health consumer movement.

I am deeply concerned that the recent arrangement to bring all decisions about PBS subsidy within Cabinet will undermine, and if maintained, destroy the transparent and accountable system which has been developed.

In 1996 I was awarded Membership of the Order of Australia (AM) for services to the health consumer movement and to the National Health and Medical Research Council (NHMRC). I am currently the consumer representative on the Advisory Committee on Prescription Medicines. I was a consumer representative and later, ministerially appointed Vice Chair of the Australian Pharmaceutical Advisory Council (APAC) from its inception until my resignation in 2000. I am an honorary life member of Consumers Health Forum and was its elected chair from 1990-5.

I have been actively engaged in the issues related to medicine policy in Australia from a consumer perspective for over twenty years. I was part of a multi-sector committee which developed the Australian National Medicine Policy, accepted by both Labor and Coalition governments and published in its current form in 1991. The policy establishes a partnership approach to manufacture, regulation, provision and use of medicines. It emphasises the interdependence issues of safety, access and quality use.

Through my involvement I have actively promoted the concerns of consumers to have a timely and transparent regulatory system for medicines and have witnessed gradual improvements in many aspects including the Pharmaceutical Benefits Scheme processes:

- An increasingly sophisticated cost/benefit analysis has been applied giving consumers and the community confidence that they are getting value for money.
- Transparency of the process has been improved, firstly through the involvement of a consumer representative on the committee and more recently with public hearings
- Sponsors are being required to address quality use of medicines principles in market proposals to ensure the most appropriate use of their products.

This rational process is both transparent and accountable. Taken with the other improvements, to labeling, information and professional education and to the quality use work of the National Prescribing Service (NPS) consumers have access to effective affordable medicine with information to assist in their appropriate use. It is a process admired internationally.

The government of the day has always had the power to engage in price negotiation and to consider recommendations where the projected cost is of significant impact to the budget. However, the current action of withholding or delaying approval of all products recommended for PBS coverage undermines the rational, accountable and transparent process which has been built up.

I have several significant concerns about the current government decision to defer listing on the PBS of medicines which have been recommended by the Pharmaceutical Benefits Advisory Council (PBAC):

1. **Risk to the viability of the current determination process by PBAC**

All of the evaluation advisory processes in the medicine regulatory regime depend on the independent expert advice of clinicians, other relevant professionals and of consumer representatives. Although sitting fees are paid these people usually do this work in addition to other full time employment. Because of the workload and the inherent risks of litigation in this highly contentious field it is difficult to identify and retain appropriate people to participate. If the evaluations of PBAC are routinely to go through a filter which delays or prioritises within a cabinet process it is unlikely that the experts currently available will feel their work and time justified. The likely outcome for government will be to draw the process into the department where the range of expertise and independence does not lie. This will undermine both the independence of the assessments and the transparency of the process.

2. **Weakening the contribution of consumers to a rational process**

Evaluation of medicines for marketing and for subsidy used to be based solely on the judgement of clinicians. It has now been acknowledged that the community values and consumer interests need to be considered. This has been achieved *inter alia* by the membership of consumer representatives on medicine evaluation committees. Generally, the Minister appoints these representatives from nominees of the national peak body, Consumers Health Forum of Australia (CHF). These representatives who have received training are supported by the organisation to enable them to consult through the network of member groups. While there are some limitations to this because of the commercial-in- confidence nature of material before committees it is clear that the contribution of a "consumer expert" adds validity and credibility to the determinations of the committees.

The presence of a consumer on these committees, including PBAC, provides an additional level of transparency to the process from a consumer perspective and modifies any perception of undue industry influence.

Trained consumer representatives understand the competing interests of individual consumers and of particular groups with experience of specific conditions and diseases. Consumers endorse the criteria for evaluation on PBAC because they ensure that need and effectiveness, rather than demand or individual interest lobbying influences outcomes.

3. **Exposing government to avoidable pressure**

While governments of the day must set the policies and oversight the practices under regulations they are wise if they remain a step removed from the day to day decision making. In the case of medicine regulation the community is well served by a sound set of processes, accepted by all stakeholders. One of the benefits is that it reduces the risk of direct pressure from powerful groups to the exclusion of the least powerful. Pharmaceutical companies, large medical research and professional groups are well positioned to engage in such lobbying. Individual and consumer groups are not.

The long term outcome risks the collapse of the whole rational edifice on which medicine policy has been built in Australia.