Submission to the Senate Finance and Public Administration Committees Inquiry into the Government's Administration of the Pharmaceutical Benefits Scheme (PBS)

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hepatitis australia

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Introduction

Hepatitis Australia was formed in 1997 as the national peak body for the state and territory hepatitis community organisations who are our members.

The mission of Hepatitis Australia is to ensure effective action on hepatitis B and hepatitis C to meet the needs of all Australians. We do this through national leadership and advocacy and by forming strong partnerships with organisations and individuals who share our goals.

We advocate strongly to improve services for all people affected by hepatitis B and hepatitis C. We pay particular attention to those groups which are at higher risk of hepatitis B or hepatitis C infection and those groups which have a disproportionate burden of chronic disease. These include: people from culturally and linguistically diverse backgrounds, Aboriginal and Torres Strait Islander peoples, children born to mothers with chronic hepatitis B, people in custodial settings, people with a history of injecting drug use, and new, and potential injectors.

Hepatitis Australia appreciates the opportunity to make this submission to the Senate Finance and Public Administration Committees Inquiry into the Government's administration of the Pharmaceutical Benefits Scheme (PBS).

The Terms of Reference of the Inquiry focus on the Government's administration of the Pharmaceutical Benefits Scheme (PBS), with particular reference to:

(a) The deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee
(b) Any consequences for patients of such deferrals
(c) Any consequences for the pharmaceutical sector of such deferrals
(d) Any impacts on the future availability of medicines in the Australian market due to such deferrals
(e) The criteria and advice used to determine medicines to be deferred
(f) The financial impact on the Commonwealth Budget of deferring the listing of medicines
(g) The consultation process prior to the deferral
(h) Compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010
(i) Any other related matter.

Hepatitis Australia

Hepatitis Australia wishes to make the following comments in relation to the Terms of Reference.

The deferral of listing medicines on the PBS that have been recommended by the Pharmaceutical Benefits Advisory Committee

The PBS, which was established over 60 years ago, is a vital component of the health care system ensuring universal access to affordable, cost effective and quality medicines. The vast majority of current government expenditure on prescriptions relates to concessional card holders.

By listing a medicine on the Pharmaceutical Benefits Scheme (PBS), the Australian Government subsidises the medicine to make it affordable to health care consumers. Varying levels of co-payment apply to PBS listed prescriptions; however, without government subsidies, many, if not most medicines are not financially accessible to the average health consumer.

Prior to February 2011

Generally, prior to February 2011, the listing of medicines on the PBS was a routine process and it was rare for the Pharmaceutical Benefits Advisory Committee (PBAC) recommendations to be ignored by any incumbent government. The PBAC, the statutory body appointed by government to provide independent and expert advice on PBS listings, applies technical and transparent standards to PBS applications to assess the clinical need for a new medicine and the value for money it demonstrates through cost-effectiveness analysis, including comparisons to other similar medicines already listed on the PBS. The degree of scrutiny applied to the PBAC assessment is intense; it is one of the most rigorous assessment processes in the world and serves to maintain much lower prices for medicines than many other countries.

Prior to February 2011, if a new medicine was recommended for listing on the PBS by the Pharmaceutical Benefits Advisory Committee and the financial implications for the Federal Government were below $10 million per year, the Minister of Health would almost invariably make a decision based on the advice and recommendations of the PBAC. The pricing for the medicine would then be set with the Pharmaceutical Benefits Pricing Authority and the new medicine would be listed on the PBS.

Cabinet review for all medicines which might exceed the $10 million per annum threshold has been in place since 2001. This Cabinet assessment process has been associated with substantial delays exceeding 12 months in some instances.

Since February 2011

Since February 2011, the Federal Government has referred all the PBAC recommendations to Cabinet, and has departed from the norm by making decisions to defer listings of drugs which have been recommended for listing by the PBAC. In February 2011, Cabinet deferred PBS listings for seven (7) new medicines

and one (1) new vaccine despite favourable recommendations by the PBAC. The length of the deferral is unknown. Minister Roxon has stated they are temporary deferrals and the medicines will be reconsidered when 'circumstances permit'. The reason for the February 2011 Cabinet decision to defer PBS listings has been linked to the government's budget deficit and stated intention to return the Federal Budget to surplus by 2013. The clear expectation was that further deferrals could be expected until a budget surplus was achieved.

The pharmaceutical industry has an interest in selling its product for the best price possible and the government has an interest in containing health care costs. The purpose of the PBAC is to stand between these two interests and independently make expert judgements about both the clinical need for new medicines and what represents value for money.

The change to the PBS listing process in February 2011 represents one of the most significant changes to the PBS listing process in recent years and has major implications for consumer access to quality medicines for prevention, management and treatment.

Hepatitis Australia does not deny that Cabinet has the 'right' to make the final decision on what is, or is not listed on the PBS, however, in our opinion, prior to departing from the established model of decision-making the government should have:

- consulted broadly with stakeholders including health care consumers
- allowed time for considered feedback from consumers and health experts on the consequences of any delay in PBS listings
- considered the merits of other cost-control methods across the PBS as a whole rather than focusing on applications for new listings
- considered the criteria to be applied by Cabinet when reviewing which medicines to approve and which to delay, and made that criteria absolutely transparent to stakeholders
- considered more fully the longer term implications of the changes, including consumer loss of confidence in the government due to the politicisation of the PBS listings and lack of transparency in Cabinet decision-making.

Any consequences for patients of such deferrals

Hepatitis Australia does not propose to make any specific comments about consequences for patients flowing from the particular medicines which have already been deferred.

In general, delays in listing of PBS medicines already approved by the PBAC mean that consumers now have an indeterminate period of time to wait for necessary and potentially life-saving medicines to become accessible to them.

Hepatitis Australia

Two new hepatitis C treatment medicines are due to be considered by the PBAC in the immediate future. In clinical trials, the addition of either one of these drugs has resulted in significantly improved cure rates compared to the current standard treatment. We are certainly aware of people who have been delaying commencement of treatment until the new medicines become available.

The February 2011 decision to defer PBS listings has created nervousness amongst our own constituents. Those who were delaying treatment until the new hepatitis C therapies became available are now wondering if they should start treatment with therapies that have much lower cure rates, or keep waiting and hope that the new therapies are approved before their liver disease progresses any further, which in itself would make a cure harder to achieve.

As the Cabinet process is non-transparent, it is impossible to know if the politicians who are now making decisions have critical information available to them. For example, deferring the hepatitis C treatment drugs would work against the goals of the Third National Hepatitis C Strategy which was approved by all of Australia's Health Ministers in 2010. We clearly need to avoid a situation where two different government policies work against each other because those making the decisions are not well informed.

Any impacts on the future availability of medicines in the Australian market due to such deferrals

The Minister indicates that the deferrals of PBS listings since February are 'temporary' and they will be reconsidered at a later date. Those people and stakeholders most affected by the deferrals are referring to them as 'indefinite deferrals' and this nomenclature will almost certainly continue until the government makes clear its intentions and puts a system and timings in place for reconsideration of all of the deferred medicines.

Once trust in the established PBS approval system has been lost, a level of cynicism is to be expected, particularly regarding the governments future intentions.

The uncertainty and lack of confidence created by a non-transparent process for PBS listing may lead some Pharmaceutical Companies to reconsider whether to invest in making applications for listing of their products in Australia. The impact of Pharmaceutical Companies withdrawing from the Australian market would most likely have some dire consequences for access to quality medicines generally.

The criteria and advice used to determine medicines to be deferred

By way of explaining the rationale for the change (after it had been implemented), Minister Roxon, in her address to the Consumers Health Forum PBS Summit, indicated that governments, rather than the PBAC have a responsibility to consider the overall priorities across the health portfolio as well as to consider the merits of spending in

the health portfolio compared to other portfolios. She cited the $137 million required to continue the Bowel Cancer Screening Program as one such competing priority.

Cabinet's chief concern when deferring PBS listings was to support achievement of the Prime Minister's pledge to deliver a budget surplus by 2012-13. How this fiscal imperative was applied to the decision-making process for individual medicines is not known. It is not reasonable to expect Cabinet to have either the time or expertise to understand the highly technical evidence put before the PBAC in relation to clinical need and cost-effectiveness. It is reasonable to expect that health care consumers will continue to have access to quality medicines based on an expert and transparent system of assessment.

The existence and nature of the assessment criteria applied by Cabinet to their decisions to defer certain medicines but not others was called into question at the May 2011 Senate Estimates hearing. When questioned about the criteria used by Cabinet to defer PBS listings, the Secretary of the Department of Health and Ageing, Jane Halton, was not able to confirm whether a set of criteria actually existed.

As an organisation, Hepatitis Australia supports the government's push for transparency as part of the National Health Reforms and believes this principle should also be applied to the Cabinet decision-making processes around PBS listings.

The capacity of Cabinet to be involved in detailed decisions about individual medicines should also be examined. Substantial delays are already encountered when Cabinet reviews PBS applications in excess of $10 million per annum; such delays have exceeded 12 months. It therefore has to be questioned whether Cabinet has the time to review all the PBAC-approved listings in any meaningful way, regardless of the advice it may, or may not be receiving.

The Minister indicated that Cabinet takes expert advice from the PBAC, the Department of Health, and the Chief Medical Officer when making their decisions. However, the PBAC is an independent statutory authority established by the Australian Government for a specific job — to provide the Australian Government with expert advice on which medicines to list on the PBS. If this advice is then overridden by alternative advice from other sources, it brings into question the legitimacy and purpose of having an independent statutory body like the PBAC in the first place.

By ignoring some of the Pharmaceutical Benefits Advisory Committee recommendations but accepting others, the Federal Government has replaced a rigorous system of expert assessment with an opaque Cabinet decision-making process based on unknown criteria. The rationale applied by Cabinet when placing a tick against some medicines and a cross against others is a complete mystery. The goal posts haven't just been moved, they have gone missing, and confidence in the process of listing medicines on the PBS has consequently evaporated.

The financial impact on the Commonwealth Budget of deferring the listing of medicines

Hepatitis Australia understands that the costs associated with the PBS and health care generally have to be sustainable into the future, and therefore cost-control mechanisms need to be considered and priorities within and across portfolios examined. However, Australia's health care system is not in crisis, the balance between health expenditure and health outcomes is reflected in the 2010 Australian Institute of Health and Welfare report. This indicates that Australia's expenditure on health is similar to the OECD median and on population-based health care indictors, such as life expectancy at birth where we are amongst the highest in the world.

How much can deferred PBS listings slow PBS expenditure and contribute to the achievement of a surplus budget by 2012-13? Are the benefits of this short-term cost containment strategy outweighed by the health care costs incurred due to poorer health outcomes in those individuals unable to access necessary and potentially life-saving medicines? Hepatitis Australia does not believe that the Australian Government has given sufficient attention to examining these two financial impact questions.

The consultation process prior to the deferral

Hepatitis Australia was both surprised and shocked by the Gillard government's decision in February 2011 to depart from the established practice and defer PBS listing of seven (7) medicines and one (1) vaccine which had been formally assessed and recommended for listing by its own government-appointed advisory body, the Pharmaceutical Benefits Advisory Committee.

This decision appears to demonstrate a disturbing lack of respect for health consumer consultation prior to instigating major changes in established practice which have a direct impact on the health and well-being of people in need of subsidised quality medicines.

Conclusion and recommendation

Hepatitis Australia considers that the process for Cabinet review of the PBAC recommendations for all medicines under the $10 million per annum threshold commenced in February 2011 is extremely flawed and problematic.

In line with consumer expectations around transparency of decision-making, Hepatitis Australia calls for a return to the established system of approvals for PBS listings in place prior to February 2011. In addition, Hepatitis Australia calls for consultations with major stakeholders including health consumer groups prior to implementation of any proposed changes to the system of PBS listings which ensure access to affordable necessary and potentially life-saving medicines to all Australians.

Contact for further information

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