Chapter 5

Consequences for patients

> Listing new therapies on the PBS is a key investment in the health of Australians and not a mere cost. These are therapies that have been shown to meet a clinical need and improve health outcomes, for example, increase survival or greater quality of life, often saving costs elsewhere in the healthcare system. Another benefit is that these medicines increase the offering of therapies to meet individual patient needs, which otherwise would not occur if there was a 'one size fits all approach' to managing illnesses in Australia based on few PBS listings...people in need of new medicines recommended for listing by the PBAC on the basis they are effective and a worthwhile investment of taxpayer money should not have access denied due to (indefinite) PBS listing deferral. Such delay may potentially create a two tiered system whereby only those able to pay fully for new non-PBS listed medicines can access them, while many Australians with serious illnesses are denied access. Is this what Australians want?
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> The PBS is a fundamental investment in Australians' health, and is not a cost containment tool to help manage the Federal Budget back to surplus.[1]

Introduction

5.1 The effects of the Government's decision to defer the listing of medications on the Schedule of Pharmaceutical Benefits (the Schedule) on patients, particularly in relation to the affordability and accessibility of medications, and the associated repercussions for individual and public health were made abundantly evident throughout the committee's inquiry.

5.2 Evidence received by the committee indicates that the Government's deferral decision is likely to result in an increased financial impost on patients who may already be struggling to pay for existing medicines, and as a result, unsubsidised medications may be inaccessible to a proportion of patients, resulting in inequitable access to the most appropriate treatment. Further, inability to access appropriate treatment entails risks not only to the health of individuals, but also to public health, and will result in further strain on the health system.

5.3 The Consumers Health Forum of Australia (CHF) informed the committee that it has seen an unprecedented level of concern from consumers about the changes to the Pharmaceutical Benefits Scheme (PBS) listing process. Following the deferral announcement, the CHF undertook a survey of the views of consumers, and 95.1 per

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1 iNova Pharmaceuticals (Australia), *Submission 11*, p. 2.

cent of respondents indicated that they are concerned about the Government's decision.[2]

5.4 Ms Liliana Bulfone of Deakin University commented that the long-term effect on patients who are unable to access deferred medicines may not be known, but stated 'to say that they are not disadvantaged I think is wrong'.[3]

Financial impost

5.5 Submitters noted that the PBS plays a central part in ensuring the affordability of medicines. Without medicines being listed on the PBS, many appropriate medications would be out of the financial reach of patients.[4] The Council of Social Service (COSS) Network noted that many low-income and disadvantaged Australians already struggle financially to access medicines which are subsidised under the PBS.[5] National Seniors Australia provided similar comments and noted that there are some older Australians, including concession card holders, who defer buying subsidised medicines because of the co-contribution they have to make.[6]

5.6 It was noted that medicines are only one of the financial burdens carried by patients. Submitters commented that patients also face out-of-pocket expenses for tests, surgery and other medical procedures, loss of income, and travel expenses, especially for patients from rural and regional areas.[7]

5.7 The Chronic Illness Alliance noted that those with chronic illness already spend a large proportion of their household income on medicines which are PBS listed, and often go without other essential items in order to afford their medicines, as health expenditure is rarely discretionary.[8] This was demonstrated by a survey undertaken by the Chronic Illness Alliance in 2003 of people in regional Victoria with chronic illness. The survey found that households with chronic illness in rural and

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2 Consumers Health Forum of Australia, *Submission 9*, Attachment A 'Keep your Cabinet out of our medicines: Results of a consumer survey on changes to the PBS listing process', April 2011, p. 4. See also Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, pp 39–40.

3 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 4.

4 Council of Social Service Network, *Submission 7*, p. 4; Cancer Voices Australia, *Submission 8*, p. 2; Private Mental Health Consumer Carer Network (Australia), *Submission 1*, p. 2; Research Australia, *Submission 12*, [p. 3]; Roche Products, *Submission 39*, p. 4; Brain Tumour Alliance Australia, *Submission 17*, p. 2.

5 Council of Social Service Network, *Submission 7*, pp 4–5.

6 National Seniors Australia, *Submission 50*, p. 1.

7 Cancer Voices Australia, *Submission 8*, p. 2; Brain Tumour Alliance Australia, *Submission 17*, p. 2.

8 Chronic Illness Alliance, *Submission 4*, pp 3–4; Council of Social Service Network, *Submission 7*, pp 4–5; Australian Pain Management Association, *Submission 14*, p. 5.

regional Victoria will pay for their health needs regardless of income, and spend more on PBS and over-the-counter medications than any other health-related item. However, as a result, these families experience considerable poverty and financial distress, and will go 'without other essentials such as food, heating, family holidays and recreation and clothing in order to pay for essential medicines'.[9]

5.8 It was also noted that those with mental illness also find it difficult to find and retain employment and are often on disability support or are homeless and therefore under financial distress.[10]

5.9 Multiple Sclerosis (MS) Australia also commented on the vulnerability of those with chronic conditions to shifts in government policy:

> People with chronic illnesses that are reliant on the health and welfare system are far more vulnerable to shifts in public policy than other Australians and have fewer options in being able to adapt to new arrangements – particularly if they have negative consequences (such as reduced access to supports, higher levels of compliance or higher costs).
>
> Their lives are already compromised in terms of employment, community participation and overall quality of life, and decisions such as the deferrals are a visible reminder of their vulnerability.[11]

5.10 The Government's decision to defer the listing of medicines was characterised as 'a form of cost-shifting' to consumers. Concern was voiced that consumers, some already burdened with high health-related costs, may now have no option but to purchase medicines which are not listed on the PBS in order to obtain the treatment most suitable for them or to go without the medicines altogether. GlaxoSmithKline Australia (GSK) stated:

> Continuing deferral of PBS listing for medicines transfers an increased proportion of the costs of important medicines from the Government to the patient. This will force some patients to make difficult choices about their medical care according to their capacity to pay.[12]

5.11 This was illustrated by evidence provided by Mr Robert Pask, who informed the committee that as a person with multiple sclerosis, he spends over $250–$300 per month on medications. Mr Pask also suffers from narcolepsy but is not in a position to afford the approved anti-fatigue medication for this condition which would cost an extra $300 per month:

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9 Chronic Illness Alliance, *Submission 4*, p. 4.

10 Private Mental Health Consumer Carer Network (Australia), *Submission 1*, p. 2.

11 MS Australia, *Submission 43*, p. 6.

12 GlaxoSmithKline Australia, *Submission 44*, p. 9. See also Chronic Illness Alliance, *Submission 4*, p. 3; AstraZeneca Australia, *Submission 47*, p. 1; Medicines Australia, *Submission 36*, p. 13.

> I am not in a position to afford it and I am lucky enough that I can get through most days without falling asleep. When you add that on you can be looking at $600 a month.[13]

5.12 It was strongly argued that any decision which results in cost shifting to patients is unacceptable, as Ms Carol Bennett of CHF explained:

> The issue is that it certainly does create huge barriers to access to treatment for the most disadvantaged people—the people who have chronic conditions who cannot work full-time because they are ill and simply do not have the income to purchase these medicines when they are not subsidised. We hear stories all the time about people having to make really difficult choices about whether they buy a medicine or whether they put food on the table, pay their electricity bill or whatever—and this is for when drugs are subsidised. When drugs are not subsidised, it puts them out of the reach of many consumers.[14]

5.13 Further, if approved medicines are not subsidised under the PBS, submitters argued that patients, as taxpayers, are in effect paying twice for medicines:

> Patients denied PBS access to such cost effective medicines because they have been deferred, who choose to pay the full cost themselves, will in effect be paying twice for their medicine.[15]

5.14 The committee received direct evidence of the impact of the cost of medicines not listed on the PBS on consumers. Ms Elizabeth Graham submitted:

> The deferral of the listing of these medications means the burden of cost remains with patients who need them. In my own case, the monthly cost of treatment by medication is considerable; the need to continue with an efficacious medication which is unlisted adds to my burden. While I can afford it, I will continue with its use, but fear the time will come when my financial situation will make it necessary to change to a PBS listed medication. Should this scenario become reality, I will be forced to use other medications to counteract the side effects of the PBS listed medication; this is a situation of false economy as additional medications will be those listed on the PBS. I am certain I am not alone in facing this situation.[16]

5.15 The COSS Network argued that as a result of the decision to defer listings, inequitable access to medicines for low-income and disadvantaged Australians will be

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13 Mr Robert Pask, National Advocates Program, Multiple Sclerosis Australia, *Committee Hansard*, 21 July 2011, p. 42. For another example, see Mr John Stubbs, Executive Officer, Cancer Voices Australia, *Committee Hansard*, 25 July 2011, p. 46.

14 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, pp 39–40.

15 GlaxoSmithKline Australia, *Submission 44*, p. 9.

16 Ms Elizabeth Graham, *Submission 54*, [pp 1–2].

exacerbated.[17] This point was illustrated by one of the respondents to the CHF survey who commented 'I am one of the people who need some of these new drugs, and being on a pension I cannot afford them unless they are on the PBS'.[18]

5.16 Submitters and witnesses also argued that the deferral decision may result in a two-tiered system in which the most appropriate medicine for some patients will be beyond their financial reach, and will only be accessible to those with the financial capacity to purchase unsubsidised medicines:[19]

> My concern is that, with that sort of a decision, we are heading more down the path of a two-tiered health system, where if you are wealthy you can afford the more convenient treatments. I know there are arguments about compliance, injections and once a month or twice a month—there are arguments about those sorts of things—but if you are wealthy you can afford to get them. If you are not, you have to rely on what is on the PBS. My concern is that, by going down this path, you are increasingly heading to a stage where all the older and less effective or less convenient and cheaper stuff is on the government scheme, but there is a range of treatments that are newer, better and can be more convenient for patients, and it will be the wealthy who will be able to access those, not the less wealthy.[20]

5.17 Although many consumers do not choose to purchase unlisted medicines, for those that do, the financial impact is large. Mr Brian Stafford commented that paying for the most appropriate medicine to treat a condition when that medicine is not listed on the Schedule can have significant financial ramifications for patients and their families:

> At the outset of the illness we owned 3 houses. By the time of the patient's death all the properties had been sold in order to pay our bills over the period of the illness. Not only is it the cost of expensive medications it is the years of lost earnings from work for the person who has to give up paid employment in order to become a full time carer. I now live in a rented house without sufficient capital left to buy any home for myself. However, my family member who was ill for some 10 years received the best medical care and medications because they were needed and they worked.[21]

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17 Council of Social Service Network, *Submission 7*, pp 4–5. See also Health Consumer's Council (WA), *Submission 33*, [p. 2].

18 Consumers Health Forum of Australia, *Submission 9*, Attachment A 'Keep your Cabinet out of our medicines: Results of a consumer survey on changes to the PBS listing process', April 2011, p. 4.

19 National Association of People Living with HIV/AIDS, *Submission 6*, p. 4; iNova Pharmaceuticals (Australia), *Submission 11*, p. 2; Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25.

20 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 32.

21 Mr Brian Stafford, *Submission 3*, p. 1.

5.18 Pfizer Australia further submitted that even if a patient is financially able to purchase unlisted medicines, these medicines may not always be available if they are not listed:

> Even if the patient is able to self fund there is no guarantee a medicine will be available privately as the manufacturer may not be able to support the medicine without PBS subsidisation. Furthermore, if a medicine is not listed on the PBS, this may affect availability in hospitals.[22]

5.19 Diabetes Australia also pointed to other costs to consumers of the deferral of medicines: if the best medication for a condition is not available, the consumer may face escalating healthcare costs as effective treatment is delayed.[23]

5.20 Mr Jose Vieira of AstraZeneca Australia also addressed the costs of the deferral to consumers and argued that sometimes the alternative medicines can also offer patients cost-savings in terms of their treatment.[24] This point was illustrated with reference to Symbicort®, provided by AstraZeneca Australia for the treatment of chronic obstructive pulmonary disease (COPD), and the alternative medicine, Seretide®, currently available under the PBS:

> Each pack of Seretide® contains sufficient doses to provide for one month's worth of therapy for COPD. In contrast, each pack of Symbicort® contains sufficient doses to provide for two month's worth of therapy for COPD. Thus, over the period of a year, a patient receiving Symbicort® for COPD will pay for 6 prescriptions (with each pack of Symbicort® lasting 2 months). By comparison, a patients receiving Seretide® for COPD will pay for 12 prescriptions (with each pack of Seretide® lasting one month). As can be seen from Table 1 below, the net result is that patients pay twice as much for treatment with Seretide® for COPD as compared to Symbicort®.

Table 1 Annual cost to patients with COPD treated with Symbicort® and Seretide® respectively

Product	Cost per prescription		Scripts/year	Annual cost to patient	
	Concessional	General		Concessional	General
Symbicort®	$5.60	$34.20	6	$33.30	$205.20
Seretide®			12	$67.20	$410.40

> It should be noted that an increase in patient co-payments means that patients contribute more to the cost of their medicines. Subsequently, because a COPD patient pays less for Symbicort® (compared to Seretide®), Government pays more. This aspect was the key motivation for the decision to defer the PBS listing of Symbicort® for COPD, which suggests a preference to shift costs from the Government to patients.[25]

22 Pfizer Australia, *Submission 35*, p. 14.

23 Diabetes Australia, *Submission 5*, [p. 1].

24 Mr Jose Vieira, Managing Director, and Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, pp 19 and 22.

25 AstraZeneca Australia, *Submission 47*, p. 5.

5.21 The Northern Territory Government Department of Health submitted that it has a mechanism in place to provide affordable access to essential medicines which have not yet been listed under the PBS:

> The Department currently has a policy to facilitate access to essential medicines where the cost of medicines would otherwise serve as a barrier. Under this arrangement, medicines that are deemed to be essential by medical specialists but are not covered by the Australian Government subsidy arrangements will have the costs met by the Department.
>
> Where a medicine is initiated while it is still under consideration for PBS listing, the Department meets the full cost until such time as it is listed...This effectively provides a safety net for limiting the consequences to patients of such deferrals.[26]

Access to medicines

5.22 Many submitters were of the view that the Government's deferral decision jeopardises access to alternative medicines for Australian health consumers, and also increases the delay patients experience in accessing affordable treatments which have been already assessed as cost-effective by the Pharmaceutical Benefits Advisory Committee (PBAC).

Access to alternative medicines

5.23 Submitters argued strongly that patients should have access to the latest and most effective treatments and the medicines which best suit their individual needs. A medicine which is an alternative to existing medication, which does not have unacceptable side-effects, should be available on the PBS.[27] Dr Simon Fisher from AstraZeneca Australia provided the committee with an example to illustrate why having access to alternative medications is important for patients:

> I wanted to talk to you about one elderly gentleman by the name of George who has chronic obstructive airways disease. I treated him with the currently listed PBS medicine. He unfortunately had an adverse experience on that medicine and he came back to see me because he had stopped taking the medicine and become much more short of breath to the point where his activities of daily living—washing, cleaning, walking down the street—were now impossible. So I looked for an alternative medicine, in a hypothetical today situation, on the PBS and I realised there is no alternative medicine for him, despite one medicine being TGA registered for the treatment of chronic obstructive pulmonary disease and in fact recommended by the PBAC. That is the medicine that AstraZeneca sponsors, Symbicort. I would be unable to use Symbicort for George because it is not listed on the PBS as a consequence of this policy.

26 Northern Territory Government, Department of Health, *Submission 62*, p. 1.

27 Cancer Voices Australia, *Submission 8*, p. 2; Private Mental Health Consumer Carer Network (Australia), *Submission 1*, p. 2.

> Therefore, I would have to put George in an ambulance to take him to hospital where he would be admitted, investigated, treated and stabilised for his chronic obstructive pulmonary disease. That is the doctor-patient interface consequence of the deferral policy. It is a direct negative effect on patients.[28]

5.24 Submitters argued that deferral of listings also serve to restrict 'clinical options to prescribed medications' which in turn reduces health outcomes.[29] Ms Anna Wise, CHF, explained, in relation to Invega Sustenna®, that:

> ...with psychiatric medications it can be so tremendously difficult to find one which actually works for a person. They can have to try so many that to have an option which is clinically effective and cost effective not made available to treating clinicians could make a real difference to so many mental health patients.[30]

5.25 This argument was supported by GSK Australia, which submitted:

> The first medicine in any therapeutic class to successfully enter the market and achieve listing on the PBS is not necessarily the best and it is essential that clinicians have access to a range of treatment choices where these exist and are proven to meet the cost effectiveness criteria for listing on the PBS...the deferral of PBS listing for medicines is a barrier to healthcare and reduces the capacity of treating clinicians to make the best treatment choice for their patients. Instead of making a decision based on the clinical requirements of the patient, a doctor must also make a prescribing decision that takes into consideration the affordability of a medicine for that patient.[31]

5.26 One of the respondents to the CHF survey who was concerned about the Government's deferral decision commented, 'It seems the Government is limiting access to medicines that a lot of people will need and may not be able to afford, and changing the goal posts to do it'.[32]

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28 Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, p. 18.

29 Mr Paul Murdoch, Vice-President, Australian Pain Management Association, *Committee Hansard*, 21 July 2011, p. 45. See also Australian Medical Association, *Submission 16*, p. 2; Medicines Australia, *Submission 36*, p. 14.

30 Ms Anna Wise, Senior Policy Manager, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 41.

31 GlaxoSmithKline Australia, *Submission 44*, p. 9. See also Breast Cancer Network of Australia, *Submission 24*, p. 2; Pfizer Australia, *Submission 35*, p. 14; Ms Elizabeth Graham, *Submission 54*, [p. 2]; Fabry Support Group Australia, *Submission 60*, [p. 2].

32 Consumers Health Forum of Australia, *Submission 9*, Attachment A 'Keep your Cabinet out of our medicines: Results of a consumer survey on changes to the PBS listing process', April 2011, p. 5.

Inequitable access to medicines

5.27 A further matter raised by witnesses was the potential for increased inequity in access to medicines. It was argued that small patient groups, for example, those with brain tumours, risk becoming more disenfranchised. If the listing process becomes politicised and more open to the influence of groups with more political presence and influence, medicines for small patient groups may not receive equal consideration:

> ...the loudest groups, the most resourced groups or companies that are the most able to get the ear of government may well end up getting their drug listed on the PBS versus a small, niche-market drug for a group of consumers who may not have the same public profile or benefits to government that may be delivered from the listing of that drug. It creates a real concern.[33]

5.28 It was also argued that inequity can arise within patient groups because of delays in listing. Ms Liliana Bulfone of Deakin University used Invega Sustenna® as an example of how the Government's deferral decision 'introduces inequities' in access:

> ...if you are a patient who responds to Consta, which is the drug that was the comparator in this particular case, you have access to a subsidised drug, but if you are a patient who does not happen to respond to that drug or who has adverse events, you do not have the same equity of access to an equivalent drug, a drug that is as cost effective and as effective.[34]

5.29 While it is generally agreed that not all medicines can be listed and there will always be patients who won't have access to various medications under the PBS, Dr Brendan Shaw of Medicines Australia stated that in the past listings have been based on clinical effectiveness and health economics. The concern with the current situation is that patients will have their access to better medicines delayed for fiscal reasons as opposed to health economic reasons.[35]

5.30 Dr Fisher of AstraZeneca Australia further explained that pharmaceutical companies are trying to facilitate patient access to medicines, but that the deferral decision impedes patient access to treatment:

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33 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 38. See also Mr Matthew Pitt, Chair, Brain Tumour Alliance Australia, *Committee Hansard*, 25 July 2011, p. 46.

34 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, pp 1–2. See also Deakin Health Economics, Deakin University, *Submission 19*, p. 5; Joint submission from Cancer Council Australia, the Clinical Oncological Society of Australia and the Medical Oncology Group of Australia, *Submission 32*, p. 2.

35 Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 31.

> We as an industry are dedicated to maintaining that access and in no shape or form would we or I ever wish to consider withholding that access or slowing it down. But that is what this policy does.[36]

Delay in access to medicines

5.31 A key concern raised by submitters is that due to the deferral of the listing of these medicines, patients are experiencing a delay in accessing valuable and cost-effective treatments, which have been assessed and approved by the PBAC.[37]

5.32 Cancer Voices Australia (CVA) cited the example of Erbitux, a medicine which can extend the lives of those with late stage bowel cancer. Erbitux was deferred by Federal Cabinet in July 2010. In June 2011 the Minister for Health and Ageing announced that it would be listed from 1 September 2011, however, in the interim, this decision has left many patients unable to access Erbitux for over 15 months.[38]

5.33 A number of submitters also raised concerns with the delay in affordable access to essential medicines caused by deferrals, which in some cases remains indefinite, as there has not yet been any indication as to when, or if, those medicines which remain deferred will be reconsidered.[39]

5.34 CHF explained that these concerns do not only relate to the medicines which have already been deferred, but to the uncertainty about which medicines may be deferred into the future:

> 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.[40]

5.35 Mr Matthew Pitt of the Brain Tumour Alliance of Australia (BTAA) noted that while no specific brain tumour medicines have as yet been deferred, the possibility that they could be, and that access to new treatments might be restricted, is very concerning:

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36 Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, p. 19.

37 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, and Dr Bill Ketelbey, Country Medical Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, pp 19 and 27–28; Dr Brendan Shaw, Chief Executive, Medicines Australia, *Committee Hansard*, 25 July 2011, p. 25. See also Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 52; Sanofi, *Submission 29*, [p. 2].

38 Cancer Voices Australia, *Submission 8*, p. 2.

39 Consumers Health Forum of Australia, *Submission 9*, p. 3. See also Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 52.

40 Consumers Health Forum of Australia, *Submission 9*, p. 3.

> ...given that we are so starved for advances in treatment, the prospect that one day an effective treatment could be deferred absolutely scares us to the core. It is very worrying.[41]

5.36 Ms Helen Tyrrell noted that constituents of Hepatitis Australia are now concerned about whether they will be able to access new treatments which are due to be considered by the PBAC in the near future:

> There are two new hepatitis C treatment medicines that are due to be considered by 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.
>
> The February 2011 decision to defer PBS listings has created nervousness amongst our 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.[42]

5.37 The implications of delayed access to the most effective and appropriate treatment for a condition can be significant, as explained by GSK:

> Delays in access to the best, most cost effective medicines will mean longer periods of debilitating illness for patients, time off work, increased use of other health services and, in some cases, could be life threatening. If they continue, the impacts will flow through to the wider economy through decreased workforce participation, increasing welfare payments, increasing health and hospital costs.[43]

5.38 Mr Denis Strangman noted that both New Zealand and the United Kingdom (UK) had responded actively to address the issue of timely access to treatment for particular groups of cancers. In the UK a special fund, the Cancer Drugs Fund, has been created to provide access to promising new therapies. In relation to New Zealand he quoted from the *Pharma Times* of 7 July:

> PHARMAC [the Pharmaceutical Management Agency of New Zealand] is also creating a pathway to assess treatments more quickly for patients whose condition would significantly deteriorate or who would miss the opportunity for significant improvement during the usual time taken to assess a Pharmaceutical Schedule application.[44]

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41 Mr Matthew Pitt, Chair, Brain Tumour Alliance Australia, *Committee Hansard*, 25 July 2011, p. 48.

42 Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, pp 52, 55 and 56.

43 GlaxoSmithKline Australia, *Submission 44*, p. 10.

44 Mr Denis Strangman, Secretary, Brain Tumour Alliance Australia, *Committee Hansard*, 25 July 2011, p. 45.

5.39 Submitters also argued that delays are likely to arise from Cabinet consideration, as Federal Cabinet will now consider the listing of every new medicine, and not just those with a financial impact of over $10 million each year.[45] Ms Bennett explained to the committee that when the $10 million threshold was in place the listing approval process for high-cost items tended to be more lengthy due to the requirement for Cabinet consideration, and on this basis calls had been made to lift the threshold to ensure patients faster access to medicines.[46] CHF concluded:

> 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.[47]

Impact on health outcomes

5.40 Many submitters expressed concern that there will be adverse health outcomes for patients who are unable to meet the cost of medicines not listed on the PBS. As a result of high costs, patients may instead elect to use an alternative medicine which is listed on the PBS, but which may not be as effective, or may have undesirable side-effects.[48] The Australian Pain Management Association (APMA) submitted:

> ...if patients cannot afford the non-listed medications, they may cease medications, take the medications on a basis or frequency less than medically recommended, or utilize inferior (but cheaper) medications. Each of these consequences will have implications for the individual, especially over time. Conditions, and or symptoms, can and will worsen. Consequential medical costs, health outcomes and quality of life/functionality impacts will result.[49]

5.41 The COSS Network noted that inability to access the most appropriate treatment will impact both individual and public health:

> The Government's decision to defer the listing of pharmaceuticals recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) will mean that the most vulnerable sick consumers will be unable to afford some critical medicines and vaccines. This will have negative

45 Consumers Health Forum of Australia, *Submission 9*, p. 3; Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 36.

46 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 38.

47 Consumers Health Forum of Australia, *Submission 9*, pp 5–6. See also Cystic Fibrosis Australia, *Submission 18*, p. 2.

48 Private Mental Health Consumer Carer Network (Australia), *Submission 1*, pp 1–2; Council of Social Service Network, *Submission 7*, pp 4–5; Novo Nordisk, *Submission 23*, [p. 2]; Joint submission from Cancer Council Australia, the Clinical Oncological Society of Australia and the Medical Oncology Group of Australia, *Submission 32*, p. 2.

49 Australian Pain Management Association, *Submission 14*, pp 5–6.

> impacts on their individual health, and also the broader health and well-being of our society.[50]

5.42 CVA also voiced its concern that patients will not be receiving the best treatment for their condition due to the deferral decision:

> We are deeply concerned that medications that can provide patients with proven substantial health benefits are not being listed on the PBS and that, as a result, some Australians will not be receiving the best possible proven treatment for their medical condition.[51]

5.43 These concerns were echoed by Dr Fisher from AstraZeneca Australia, who explained that patients will continue to be treated, but the issue is that around 30 per cent of patients will have an adverse event from the medication they are prescribed, and if medicines which provide an alternative treatment continue to be deferred, these patients will be at risk of complications.[52]

5.44 Mr Stafford described the possible impact on a patient's quality of life if the appropriate medicine is not subsidised under the PBS:

> I found that the proven best treatments in our case were through pharmaceutical medications that were not subsidised on the PBS. I did not pay for the necessary medication for over 5 years because I was rich. I bought the medications because they worked. They worked in that they gave the patient a quality of life that she would otherwise have been denied.
>
> The alternative was to accept the GP's recommendations of only PBS subsidised drugs, none of which would have helped the patient, and have the patient committed to a locked institution until her death.[53]

5.45 Submitters also pointed to other benefits which may accrue from the use of alternative medicine regimes, for example, certain medicines may make 'compliance' with the treatment regimes required for various conditions easier, and therefore directly improve health outcomes.[54] A case in point is the deferred antipsychotic medication Invega Sustenna®. Mr Bruce Goodwin, Janssen-Cilag Australia, referred to the compliance benefits associated with Invega Sustenna®:

> There is a well-established body of evidence supporting the use of antipsychotic medications to reduce relapse. In particular, long-lasting injectables are shown to improve adherence to medication. In fact, around 80 per cent of patients remain adherent on long-lasting injectables whereas

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50 Council of Social Service Network, *Submission 7*, pp 4–5.

51 Cancer Voices Australia, *Submission 8*, p. 4.

52 Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, p. 21.

53 Mr Brian Stafford, *Submission 3*, p. 1.

54 Diabetes Australia, *Submission 5*, [p. 1]; Mr Bruce Goodwin, Managing Director, Janssen-Cilag Australia, *Committee Hansard*, 21 July 2011, p. 25.

> only 50 per cent remain adherent on oral medications as an alternative. Of course, if you do not take your medication you are more likely to get sick again.[55]

5.46 NAPWA also raised concerns that health outcomes would be compromised if new and improved medicines and therapies are delayed, or are withdrawn from or not made available in the Australian system.[56] Ms Tyrrell of Hepatitis Australia noted that any deferral in the treatment of Hepatitis C can have significant implications, including 'increasing liver fibrosis, cirrhosis, liver cancer, the need for a transplant, liver failure and death'.[57] In addition, submitters also argued that delay in access to medicines can impact on the longevity of patients. One respondent to the CHF survey provided an example to demonstrate that a delay in access to medicine can lead to loss of life:

> Delay in listing Azacitidine last year (recommended by PBAC September 2009, listed February 2011) meant some of Leukaemia Foundation's patients died waiting for this new drug while awaiting Cabinet approval for PBS listing[58]

Benefits of effective treatment of medical conditions

5.47 Chronic Illness Australia and other submitters explained that access to affordable medicines is important for those suffering from chronic illness, not only in terms of staying alive but also in affording them quality of life, thereby enabling them to participate more actively in the community and the economy.[59] iNova Pharmaceuticals (Australia) commented:

> Listing new therapies on the PBS is a key investment in the health of Australians and not a mere cost. These are therapies that have been shown to meet a clinical need and improve health outcomes, for example, increase survival or greater quality of life, often saving costs elsewhere in the healthcare system.[60]

5.48 Further, NAPWA noted that there is a public health benefit in the effective treatment of medical conditions such as HIV, because as the 'health of a person with

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55 Mr Bruce Goodwin, Managing Director, Janssen-Cilag Australia, *Committee Hansard*, 21 July 2011, p. 25.

56 National Association of People Living with HIV/AIDS, *Submission 6*, p. 4.

57 Ms Helen Tyrrell, Chief Executive Officer, Hepatitis Australia, *Committee Hansard*, 25 July 2011, p. 56.

58 Consumers Health Forum of Australia, *Submission 9*, Attachment A 'Keep your Cabinet out of our medicines: Results of a consumer survey on changes to the PBS listing process', April 2011, p. 5. See also Joint submission from Cancer Council Australia, the Clinical Oncological Society of Australia and the Medical Oncology Group of Australia, *Submission 32*, p. 2; Roche Products, *Submission 39*, pp 3–4.

59 Chronic Illness Alliance, *Submission 4*, p. 3; Diabetes Australia, *Submission 5*, [p. 1].

60 iNova Pharmaceuticals (Australia), *Submission 11*, p. 2.

HIV is improved the amount of virus they carry is reduced to very low levels, thus making onward transmission of the virus very difficult'.[61]

5.49 The committee also heard that effectively treating a medical condition can prevent co-morbidity, or suffering from other conditions caused by or linked to the original condition, which not only impact on the quality of life of the patient, but also create further burden on the health system in terms of resources and cost.[62]

5.50 Mr Pask of MS Australia explained to the committee what it means to him to have access to the medicines he requires:

> I have multiple sclerosis and I have type 2 diabetes—even though I do not admit to it—arthritis and a few other things, so I am dependent on so many medications. In theory, I am able to work three days a week. But I do work a lot longer than that...But I am only able to do that because the medications are there.
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> ...I do not believe we look enough at the value of medications, as far as keeping people in work and getting people back into work. Obviously, the cost benefit is what we get out of it. Because of my medications, I have been given an opportunity to keep going and keep working and doing stuff that I really love doing. But if I were not working I would not be able to afford a lot of that stuff...[63]

Consequences of not having access to the deferred medicines

5.51 As discussed in chapter 3, the committee heard that not all alternative medications are equal, and for some patients, alternative treatments are not a viable option. The committee sought to quantify the impact on patients of the Government's decision to defer particular medicines, and found that potentially the deferral of these products could affect:

- 100,000 people in Australia living with schizophrenia;[64]
- an estimated 50,000 to 100,000 Australian patients living with chronic pain;[65]
- potentially up to 40,000 patients who would be eligible for the Botox® treatment;[66]

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61 National Association of People Living with HIV/AIDS, *Submission 6*, p. 1.

62 Ms Elizabeth Trapani, and Ms Chey-Anne Ellsum, *Committee Hansard*, 21 July 2011, p. 35.

63 Mr Robert Pask, National Advocates Program, Multiple Sclerosis Australia, *Committee Hansard*, 21 July 2011, p. 41.

64 Mr Bruce Goodwin, Managing Director, Janssen-Cilag Australia, *Committee Hansard*, 21 July 2011, pp 25 and 28.

65 Mr Rob Baveystock, Managing Director, Mundipharma, *Committee Hansard*, 21 July 2011, pp 26 and 28.

66 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 20.

- almost one in five Australians over 40 years of age who are affected by chronic obstructive pulmonary disease;[67]
- about 24,000 patients over five years with venous thromboembolism;[68] and
- potentially 10,000 patients receiving in vitro fertilisation (IVF) and gamete intrafallopian transfer (GIFT) interventions.[69]

5.52 The following discussion focuses on three of the medicines deferred: Invega Sustenna®, Targin® and Botox® (for the treatment of hydohidrosis).

Case Study 1: Invega Sustenna® (paliperidone palmitate)

5.53 Invega Sustenna® is a treatment for schizophrenia which is administered monthly through an injection to the arm. While it acts in a similar way pharmacologically to another antipsychotic medication, risperidone, it differs to all other antipsychotics in the method in which it is administered.[70]

5.54 Ms Bennett noted that the CHF has received a particularly strong response from consumers about the deferral of Invega Sustenna®:

> ...largely because the concern there is that there are real issues around compliance of mental health consumers. When you have to attend a clinic and have two injections a month, versus attending a clinic and having one injection a month, that may seem fairly insignificant to the average person. But for somebody who is trying to manage their lives and has to involve a carer, has to get to a clinic and has to maintain a treatment regime and could well, if they do not take their medication, end up hospitalised and psychotic—and all the implications that go with that—that is a pretty significant quality of life impact. So, for those consumers, that stood out to me as being one of the drugs that it is pretty hard to argue that there is an alternative available for, when the alternative can mean the difference between somebody being hospitalised or not.[71]

5.55 Mr David Learmonth of the Department of Health and Ageing (DoHA) noted that the PBAC recommended Invega Sustenna® on the basis that its efficacy and toxicity is similar to the existing treatment, Risperdal Consta®, but concluded that the claim of clinical superiority was not justified on the evidence presented:

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67 Dr Simon Fisher, Medical Director, AstraZeneca Australia, *Committee Hansard*, 21 July 2011, p. 20.

68 Dr Bill Ketelbey, Country Medical Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 28

69 Dr Bill Ketelbey, Country Medical Director, Pfizer Australia, *Committee Hansard*, 21 July 2011, p. 28.

70 SANE Australia, *Submission 10*, [p. 1].

71 Ms Carol Bennett, Chief Executive Officer, Consumers Health Forum of Australia, *Committee Hansard*, 25 July 2011, p. 41.

> No benefit in reduction of relapses was demonstrated, nor was there any evidence to support the claim that this alternative drug reduces the number of days patients spend in hospital.[72]

5.56 However, a number of submitters argued quite strongly that Invega Sustenna® is an important alternative medicine. Ms Bulfone of Deakin University used Invega Sustenna® as an example to illustrate that alternative medications are not equivalent on a patient-by-patient basis:

> Invega Sustenna for schizophrenia is a really good example of where the drug on a population level results in the same average benefit to patients in a clinical trial, but for an individual patient, particularly as this drug has different pharmacological properties to its comparator, the profile of side-effects that goes with it is also different. A patient may not be able to tolerate Consta, which is currently available and was the comparator in that case, but they will be able to tolerate Invega Sustenna, or they may respond to one but not the other. Yes, there are alternatives, but they may not work.[73]

5.57 A respondent to the CHF survey also explained the value of an alternative treatment for patients who have not responded well to existing treatments:

> The Government has promised to increase funding for mental health, yet in this recent decision it has refused to allow a new drug to be listed for the treatment of schizophrenia. As with any drug that treats conditions of the brain, one drug does not suit everyone, and by refusing to allow the availability of a new drug, this Government is depriving those with schizophrenia who have not responded well to existing drugs of an opportunity to achieve good mental health. This action flies in the face of this Government's stated position on mental health.[74]

5.58 SANE Australia commented that, for people living with schizophrenia, the difference in administration of Invega Sustenna® has significant benefits, and should not be trivialised:

> A monthly injection makes adherence much more likely and reduces by half or more the number of visits to a doctor. For people whose symptoms include reduced cognitive ability and motivation, it increases the likelihood that they will attend the appointment; it also halves the attendant trouble and cost of a journey to the doctor's surgery or clinic. This in turn benefits the carer as well as freeing up the clinician's time and administration costs. A monthly injection to the arm is also more easily given, more dignified

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72 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 2.

73 Ms Liliana Bulfone, Senior Research Fellow, Deakin University, *Committee Hansard*, 21 July 2011, p. 4.

74 Consumers Health Forum of Australia, *Submission 9*, Attachment A 'Keep your Cabinet out of our medicines: Results of a consumer survey on changes to the PBS listing process', April 2011, p. 11.

> and less traumatic than a fortnightly injection to the buttock (especially where the person is being treated involuntarily).[75]

Case Study 2: Targin® (oxycodone/naloxone)

5.59 Targin® is used for the treatment of pain and has been approved by the Therapeutic Goods Administration (TGA) for managing moderate to severe pain which is unresponsive to non-narcotic pain relief medication.[76] Respondents to the CHF survey commented that Targin® has benefits over other available 'alternatives' in that it provides a substitute for the more addictive Oxycontin, and 'as a combination of oxycodone and naloxone cleverly avoids the opioid bowel dysfunction seen with other opiod analgesics and reduces significantly the potential for abuse'.[77]

5.60 Submitters explained that Targin® has the potential to reduce the abuse and diversion of strong prescription opioids, and is 'the first opioid analgesic that incorporates abuse deterrence technology to help address this major community issue'.[78]

> Opioid diversion is something we cannot just push aside; it is becoming a much, much bigger problem throughout the world. This preparation would be extremely unattractive to opioid abusers because it is not designed for intravenous use. If it was injected intravenously, because of the blocking drug contained in the preparation it would cause an immediate and very severe withdrawal. It is the start of our abilities to provide pain management with a specifically designed preparation that will not have any appeal whatsoever to opioid abusers.[79]

5.61 The committee was told that it is difficult to quantify the potential for reduced drug diversion and abuse, and insufficient evidence on this characteristic was provided to the PBAC for a definite conclusion.[80] While the technology incorporated into this medicine will not stop abuse entirely, from a practitioners point of view:

> ...at least it would overcome the problem, when we are prescribing the current range of opioid drugs for a patient with medical indications, of us

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75 SANE Australia, *Submission 10*, [p. 1]. See also Ms Barbara Hocking, Executive Director, SANE Australia, *Committee Hansard*, 25 July 2011, pp 49–50; Research Australia, *Submission 12*, [p. 4].

76 Mundipharma, *Submission 38*, p. 5.

77 Consumers Health Forum of Australia, *Submission 9*, Attachment A 'Keep your Cabinet out of our medicines: Results of a consumer survey on changes to the PBS listing process', April 2011, p. 11. See also Mr Rob Baveystock, Managing Director, Mundipharma, *Committee Hansard*, 21 July 2011, p. 26.

78 Mr Rob Baveystock, Managing Director, Mundipharma, *Committee Hansard*, 21 July 2011, p. 26.

79 Professor Michael Cousins, Director, Painaustralia, *Committee Hansard*, 21 July 2011, p. 44.

80 Emeritus Professor Lloyd Sansom, Chair, Pharmaceutical Benefits Advisory Committee, *Committee Hansard*, 25 July 2011, p. 23.

> having to be concerned that this drug might, by various means, be diverted to other users.[81]

5.62 Mr Learmonth of DoHA noted that in its PBAC submission Mundipharma did not claim that Targin® was superior to the currently available oxycodone in combination with over the counter laxatives.[82] However, in its submission, Mundipharma explained that opioid-induced constipation has distinct causative factors, and laxatives do not address the cause of the condition, rendering them a 'less than adequate treatment'.[83]

5.63 Mr Rob Baveystock, Managing Director, Mundipharma, added that while there are opioid analgesics available to treat chronic pain, these treatments have shortcomings:

> Whilst these medicines are undoubtedly effective in relieving severe disabling pain, they are also potentially associated with serious side effects, including opioid-induced bowel dysfunction, often including severe opioid-induced constipation, and potential for addiction. What is apparently not understood by government is that this is not the type of constipation that otherwise healthy individuals might suffer from time to time. It is far worse; it is almost inevitable; it results in increased cost to the community and government; and, importantly, it cannot be treated with simple laxatives. Severe constipation can lead to impaction and hospitalisation and can aggravate cancer pain, resulting in a pattern of increasing opioid dosages in an attempt to relieve pain...there is no strong opioid analgesic available in Australia which treats chronic disabling pain while simultaneously addressing the cause of opioid-induced constipation and helping to prevent it.[84]

Case Study 3: Botox® (botulinum toxin type A)

5.64 Botox® has been TGA registered for the treatment of severe primary hyperhidrosis of the axillae (underarms). This condition manifests through severe, excessive sweating, and as a result, patients suffer constant wetness and staining of clothing, and dehydration and maceration of the skin, which can result in secondary skin infections. Patients can also experience difficulty in grasping objects and writing. Effective treatment can improve the social functioning and mental health of those

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81 Professor Michael Cousins, Director, Painaustralia, *Committee Hansard*, 21 July 2011, p. 47.

82 Mr David Learmonth, Deputy Secretary, Department of Health and Ageing, *Committee Hansard*, 25 July 2011, p. 2.

83 Mundipharma, *Submission 38*, p. 15.

84 Mr Rob Baveystock, Managing Director, Mundipharma, *Committee Hansard*, 21 July 2011, p. 26.

affected by hyperhidrosis who can become withdrawn and depressed as a result of the condition and its symptoms.[85]

5.65 As recognised in treatment guidelines, Botox® provides a unique second-line treatment for those affected by hyperhidrosis whose condition is not effectively managed through prescription topical aluminium chloride antiperspirants. It also provides a less invasive treatment option prior to the consideration of surgery, which is only undertaken in a minority of patients. In making a positive recommendation for the listing of Botox® for the treatment of severe hyperhidrosis, the PBAC noted that there were no other second-line treatments for severe hyperhidrosis of the axillae on the PBS, that the condition has significant impact on the quality of life of patients, and that there was a clinical need for botulinum toxin.[86]

5.66 Submitters explained that treatment of severe hyperhidrosis through the use of lotions or surgery is not necessarily successful, and the side-effects of these options are often less than desirable. Ms Elizabeth Trapani explained to the committee that she has pursued a number of local treatment options for her daughter, Ms Chey-Anne Ellsum, who suffers from severe hyperhidrosis:

> ...we used every lotion, potion, spray and roll-on we could get our paws on. We had no luck.[87]

5.67 Given the invasive nature of the surgical option, the comparatively low success rate, the fact that it is not a permanent solution, and the potential side-effects of the surgery which can include a collapsed lung, palsy of the face and increased sweating, Ms Trapani explained 'When we found out the dangers of this surgery, it was not an option I wanted to pursue for my daughter'.[88]

5.68 Mr Mark Glover of Allergan Australia noted that in explaining why the listing of Botox® under the PBS was deferred, the minister has acknowledged that there is no alternate treatment available under the PBS, and further, has stated that hyperhidrosis is a mild condition for many people. However, Allergan Australia took issue with this reasoning, as the TGA approved indication and PBAC recommended listing for Botox® are for severe disease.[89]

5.69 Further, Botox® treatment is expensive – in Ms Ellsum's case, the initial treatment cost just under $1900, a cost which for many people is prohibitive.

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85 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 16.

86 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 16.

87 Ms Elizabeth Trapani, *Committee Hansard*, 21 July 2011, pp 34 and 36–37.

88 Ms Elizabeth Trapani, *Committee Hansard*, 21 July 2011, pp 34 and 36–37.

89 Mr Mark Glover, Vice President and Managing Director, Allergan Australia, *Committee Hansard*, 21 July 2011, p. 17.

Ms Trapani explained that they were fortunate that Ms Ellsum's grandparents were able to assist with the payments.

5.70 Ms Ellsum provided the committee with an insight into how living with hyperhidrosis had affected her life, and the difference it has made to be able to access the Botox® treatment. She also noted that if the Botox® treatment for hyperhydrosis was listed under the PBS, it would be more accessible not only for her, but also for others suffering from the same condition:

> I have had it since I was three, but it got really bad in puberty. That was when I was in high school, so I was like the magnet for bullying; everyone went at me, because they did not understand, and no-one understands. It caused my depression. There were days when I did not want to get out of bed because it is so controlling. I blamed myself lots of the times when I had it; I thought it was just me who had it. It draws people back; it stops people from doing things. It deprived me of most of my youth; I did not do the things I wanted to do because it was so controlling and conflicting with my life. I could not do my deb this year because I was afraid of what people would think, and that really made me sad.
>
> With the Botox, it has been amazing. It is the biggest improvement that I have ever heard about, and it has worked. I am planning to do my deb next year, and now I am doing all the things that I have always wanted to do. I am here now. This is not something I would have done back then. I am here because there are people out there who cannot get this. I would be stuck if it were not for my grandparents, because they are the only people who are getting me through this. I would not have this if it were not for them.[90]

Committee comment

5.71 Evidence received by the committee highlights that many Australian health consumers are under significant financial burden, particularly those with chronic illness and those on low-incomes. The PBS process should ensure that the most effective medications are available at an affordable price for all Australians. However, the Government has now introduced a further consideration to the listing of medications: an unclear, undefined fiscal hurdle with no specific timeline.

5.72 This a short-term consideration which will have adverse affects on patients. For some consumers, the deferred medicines represent a more appropriate treatment regime, or in some cases, the only effective treatment. In the committee's view, it is unacceptable that the Government is denying access to these treatments.

5.73 The committee is concerned that the Government's decision to defer the listing of certain medications will exacerbate inequitable access to medicines for low-income and disadvantaged Australians. The committee is of the view that this will lead to a two-tiered system in which only those with adequate financial capacity will

90 Ms Chey-Anne Ellsum, *Committee Hansard*, 21 July 2011, pp 34–35.

be able to access newer, more effective treatments, which will remain out of financial reach for lower-income patients.

5.74 The committee considers that timely access to affordable appropriate alternative medications is a centrally important feature of the PBS. The committee notes the consequences in terms of quality of life and adverse events of not having access to an appropriate and effective medication as illustrated by the case studies discussed in this chapter. This not only has repercussions for the health of individuals, but also for broader public wellbeing and demands on the public health system. In light of this the committee is of the view that health outcomes of Australian patients should not be compromised by restricted access to a small or pre-determined number of medicines in a given class due to the Government's budgetary considerations.