COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

FINANCE AND PUBLIC ADMINISTRATION REFERENCES COMMITTEE

Administration of the Pharmaceutical Benefits Scheme

MONDAY, 25 JULY 2011

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SENATE

FINANCE AND PUBLIC ADMINISTRATION REFERENCES COMMITTEE

Monday, 25 July 2011

Senators in attendance: Senators Boyce, Di Natale, Fierravanti-Wells, McEwen, Polley, Ryan and Williams

Terms of reference for the inquiry:

To inquire into and report 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 a deferral;

(h) compliance with the intent of the Memorandum of Understanding signed with Medicines Australia in May 2010; and

(i) any other related matter.

WITNESSES

DE CARVALHO, Mr David John, First Assistant Secretary, Social Policy Division, Budget Group, Department of Finance and Deregulation

LEARMONTH, Mr David, Deputy Secretary, Department of Health and Ageing

MARTINE, Mr David John, Deputy Secretary, Budget Group, Department of Finance and Deregulation

McNEILL, Ms Felicity, Acting First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing

PLATONA, Ms Adriana, Assistant Secretary, Pharmaceutical Evaluation Branch, Department of Health and Ageing

Committee met at 09:03

CHAIR (Senator Ryan): I declare open this meeting of the Senate Finance and Public Administration References Committee. The committee is continuing its inquiry into the government's administration of the Pharmaceutical Benefits Scheme. I welcome officers of the Department of Health and Ageing and the Department of Finance and Deregulation. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. I remind witnesses that the Senate has resolved that an officer of a department of the Commonwealth or of a state shall not be asked to give opinions on matters of policy and shall be given reasonable opportunity to refer questions asked of the officer to superior officers or to a minister. This resolution prohibits only questions asking for opinions on matters of policy and does not preclude questions asking for explanations of policies or factual questions about when and how policies were adopted. The committee has the submission by the Department of Health and Ageing. I now invite you to make a short opening statement, at the conclusion of which I will invite members of the committee to put questions to you.

Mr Learmonth: I do have a brief statement.

CHAIR: Please go ahead.

Mr Learmonth: I would like to cover a number of issues that were raised in the hearing, both matters of general principle and, in particular, to respond to a couple of specific questions that arose in the previous hearing where I think you were looking for some further comment from us.

The Pharmaceutical Benefits Scheme provides the Australian community with reliable, timely and affordable access to over 770 drugs, available in more than 1,960 forms and marketed as over 3,900 brands. In 2009-10, around 184 million PBS subsidised prescriptions were dispensed, at a cost of $8.3 billion expenditure and, in 2010-11, it is estimated to be around $9 billion. As reported in the portfolio budget statements 2011-12, in 2008-09 PBS growth was 9.2 per cent. In 2009-10, PBS growth was nine per cent. In 2010-11 and 2011-12, PBS growth is estimated to be 7.7 per cent and 6.5 per cent respectively. Since 2007, over 500 medicines or brands of medicines have been listed on the PBS, the Life Saving Drugs Program and the National Immunisation Program, at a cost of over $4 billion over five years. In 2011 alone, the government has approved and/or listed over 152 medicines, at a cost of nearly $850 million. In all this, only eight medicines were deferred by the government on 25 February this year, of which only six remain deferred. These six medicines represent less than 3.9 per cent of all listings in 2011 and less than one per cent of listings over the past four years.

I would like to take the opportunity to respond to a number of matters, as well as to clarify a response to some questions raised at Thursday's hearing. A number of submissions have pointed to the recent deferral of eight medicines as grounds for a fundamental reconsideration by the pharmaceutical industry of its investment practices in Australia, in particular its intention to bring new and innovative drugs to the Australian market. The industry is suggesting that in fact the deferrals are changing the risk rating for pharmaceutical investment in the Australian market. This assertion is made based on 3.9 per cent of all listings in 2011 being deferred, which represents less than one per cent of all listings since 2007. Pharmaceutical companies apply for PBS subsidisation in the full

knowledge that the outcome is not guaranteed. I would argue that the biggest hurdle for a company as to whether a drug ends up being subsidised on the PBS remains the PBAC, the Pharmaceutical Benefits Advisory Committee.

In 2010, 63 per cent of all first-time, cost-effective submissions were rejected by the PBAC. This is not a one-off statistic but a consistent marker of the rigour of the assessment process undertaken. It is this assessment process which I would suggest is the main decision point for companies in determining whether to bring a drug to the subsidised market in Australia.

Let us look at the evidence. Companies are still actively seeking listing on the PBS, as evidenced by the fact that there has been no change in the total number of submissions received for consideration by the PBAC over the last three months. On the contrary, the July meeting of the PBAC received a record number of submissions. This is further supported by the testimony of John Latham, of Pfizer, who acknowledged:

For critics to say that the industry are threatening to not bring new products to Australia because we do not like the system is rubbish. We are here and our job is to discover medicines and bring them to citizens around the world.

Finally, whilst eight deferrals were announced in February this year, two of these have subsequently been listed. No medicines recommended by the PBAC, at its March 2011 meeting, were deferred by the government and, by September this year, 152 new drugs or amendments to listings of existing drugs will have been listed on the PBS, reflecting the government's continued commitment to list medicines.

Many of the drugs approved by government for listing in 2011 demonstrated additional health outcomes over treatments currently available for severe or life-threatening conditions—drugs such as Soliris for PNH, Romiplostim for severe bleeding disorders and Duodopa for advanced Parkinson's disease. While there is a lot of talk of about the patient cliff that is facing many innovator companies, considerable investment is being made by these same companies to revamp their research approach towards innovative medicines that work better than existing drugs in the areas of, to name a few, oncology and Alzheimer's disease. However, most of the drugs deferred in February this year do not fall into that category. Most of these drugs were cost-minimised or 'me too' drugs, with no added efficacy or health outcome and no less toxicity than existing treatments but with a net cost to the government. For example, paliperidone long acting, known as Invega Sustenna, which is a treatment for schizophrenia, was recommended by the PBAC on the grounds that it is of similar efficacy and toxicity to the existing long-acting therapy, Risperdal Consta, but it has a net cost to government. Both of these long-acting injections are made by the same company, Janssen-Cilag. In fact paliperidone, or Invega Sustenna, is a metabolite of risperidone. This simply means that paliperidone is the substance that the body converts risperidone into when that drug is taken. Every submission to the inquiry and participant at the hearing praised the rigour of the PBAC process. With respect to Invega Sustenna, the PBAC assessed the evidence presented and concluded that the claim of superiority in clinical practice was not justified. 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.

It is true that all medicines deferred by government were recommended by the PBAC as being cost effective, but that does not mean they should be funded ahead of every other call on the government, whether in health or more broadly. It is the proper role of government to decide these things. The roles of PBAC and of government have not changed. The PBAC advises and the government decides, as has always been the case. Sometimes the government arrives at a different decision to that advised by the PBAC. The most frequently cited examples are nicotine patches in 1994 and Viagra in 2002, when the PBAC said yes and the government said no.

I turn to some of the specific questions that the committee, I think, has asked for some further information on—some of the questions raised by Mundipharma, for example, in relation to Targin in their submission and their appearance at the inquiry. Targin is a combination of oxycodone and naloxone, and a number of strong statements have been made in relation to this drug which I do need to respond to. Firstly, by deferring this drug's listing on the PBS, the government has not denied patients the right to be pain free. Oxycodone, which is the pain medication in this combination product, has been on the PBS since 2001 and remains on the PBS, with expenditure of $74 million in 2009-10. Secondly, Targin is an alternative pain management therapy to opioids alone or in conjunction with prophylactic laxatives. Naloxone, which is the drug it is in combination with, is an opioid antagonist which helps prevent constipation. I said during the May Senate estimates that Naloxone has a laxative effect. I did not say that Naloxone is a laxative; it is not. However, patients who take opioids and have constipation can manage this by taking a laxative. The PBAC noted that many people purchase over-the-counter laxatives, and the company itself did not claim that Targin was superior to oxycodone plus prophylactic over-the-counter laxatives. Thirdly, in its submission Mundipharma claims that the forward estimates savings were agreed. This is simply not true. Only the Department of Finance and Deregulation can agree costings, and no such savings

were agreed. Finally, in its submission Mundipharma claims that the Department of Health and Ageing agreed that there will be a saving from a reduction in the abuse of OxyContin tablets. My statement during the May Senate estimates that the government would not have figures showing savings from reduction in abuse and diversion stands. It is based on the PBAC's public summary document of July 2010, which states:

… the potential for reduction in illicit drug use was not based on evidence and … estimated savings to the PBS were … uncertain.

Finally, let me turn to the suggestion that the government is no longer meeting its commitments under the memorandum of understanding with Medicines Australia. It is true that the deferrals represent a change. It is also true that what the industry wanted and were looking for was stability, and that is why they proceeded with discussion and negotiation of an MOU with the government. This is different, however, to what the MOU does as a negotiated document. The MOU represents and reflects the scope of that agreement. In this case, the intent of the MOU itself is clear. Notwithstanding what anyone's motivation might have been for generating and negotiating one, the intent of the document is clear. Indeed, there is an intent clause which spells it out. Clause 3 of the MOU states:

Both parties intend that the MOU will promote the efficiency and sustainability of the PBS and support, by the provision of a stable pricing policy environment, a viable and responsible medicines industry in Australia …

Clause 4 of the MOU states:

The Commonwealth undertakes not to implement new policy to generate a price-related savings from the PBS during the period of the agreement, that is, measures that would change the ex-manufacturer price of particular medicines, other than reflected by this MOU.

This is the undertaking reflected in the MOU. This is the intent of the MOU—to provide certainty with respect to pricing and no more. Recommendations to the PBAC and the PBPA have always required government approval, and the referral of all listings with a financial impact for cabinet consideration is consistent with the commitments made under the MOU. This is not new pricing policy.

Finally, it has been suggested that the Commonwealth has departed from clause 29 of the MOU, specifically:

For those submissions required to be approved by Cabinet, the Commonwealth will use its best endeavours to implement a maximum time frame of six months for consideration and decision by Cabinet.

Since this came into effect the government has consistently met or indeed bettered this timetable for consideration, with two of the last high-cost listings being considered by cabinet within one month of pricing being agreed. I think that is the record. Thank you; I will be pleased to take questions.

CHAIR: I want to explore the issue you raised of cost minimised listings. As I understand it, cost minimised listings are where no therapeutic advantage or health outcome advantage of a proposed medicine for listing is established against an existing treatment on the PBS. Is that correct?

Mr Learmonth: The cost minimisation submission is a submission put forward by a company where it claims no superiority—or noninferiority, in technical terms. It is equivalent to something else already listed; that is quite correct.

CHAIR: And those assessments are made on a population level, aren't they? We explored an example the other day. To use a common medicine, statins, there are multiple different chemical entities on the market. I understand some either are or were linked to each other on a cost minimised basis. They all might work in 500 out of 10,000 people, but it might be a slightly different number of that 500, might it not?

Mr Learmonth: That is certainly possible. It depends on the circumstances.

CHAIR: If the government or the department, the PBAC, approves a medicine that is cost minimised, doesn't that indirectly mean that it is cost effective, because it actually traces its price back through a price link to a cost-effective listing?

Mr Learmonth: The PBAC will not make a recommendation unless it is cost effective. I am not sure what further implication you can draw from that.

CHAIR: If I list medicine B for a particular condition, I cannot establish superiority, but the PBAC has approved it as a cost minimised listing to medicine A for the same condition, which is listed as cost effective or might have another linking process right back through multiple medicines, as these work. Doesn't that by implication mean that medicine B, linked to that other price purely on a cost minimised basis—so if medicine A's price falls, medicine B's price false falls with it—is actually cost effective through the approval of the PBAC on a cost minimised basis?

Mr Learmonth: If something is approved by the PBAC in any circumstances it is considered to be cost effective, for whatever the reason.

CHAIR: I cannot remember the exact words you used in your statement; so please correct me if I am misattributing you. An additional medicine for the same treatment, which provides no therapeutic superiority and is listed on a cost minimised basis, may actually be very important to some patients because the other treatments available for that do not work for them at an individual level. Is that not true?

Mr Learmonth: It is potentially true, Senator.

CHAIR: I know there are a lot of senators here. I will discuss with the deputy chair and others some time allocations. I will hand to Senator Fierravanti-Wells and then come to Senator Polley.

Senator FIERRAVANTI-WELLS: Mr Learmonth, at page 10 of your submission, you say, 'the Government is concentrating on listing medicines that treat serious or life-threatening conditions where there are no alternative treatments' on the PBS. Why was this decision made and when was it made?

Mr Learmonth: The decision was made in February this year, just prior to the government's announcement in relation to the listings from the previous PBAC meeting. It was made in the context of the overall fiscal environment and the growth of the PBS generally and the desire to seek further sustainability in that context.

Senator FIERRAVANTI-WELLS: When precisely was it made?

Ms McNeill: The announcement was on 25 February 2011.

Senator FIERRAVANTI-WELLS: Was the decision made on that day? I am going to come to who made the decision, which is why I am asking—

Mr Learmonth: It was a cabinet decision just prior to that.

Senator FIERRAVANTI-WELLS: Can I have the date?

Mr Martine: We might need to take that on notice. It would have been earlier in the month.

Senator FIERRAVANTI-WELLS: Was it generated by Minister Roxon or was it generated by Treasury or Finance? There must have been a cabinet submission that went up. Did it come from Treasury or Finance or Minister Roxon?

Mr Martine: If my recollection is correct, this was in the context of government's consideration of new listings.

Senator FIERRAVANTI-WELLS: Mr Martine, I have asked who put up the submission. I am not asking what the submission was; I am asking who put it up.

Mr Martine: If it is a submission on new drug listings then it is a submission from the minister for health.

Senator FIERRAVANTI-WELLS: Are you confirming that Minister Roxon put up the submission? That is my question to you.

Mr Learmonth: The minister for health indeed put forward a submission to list new medicines as is normally the case after PBAC meetings.

Senator FIERRAVANTI-WELLS: So it was not something that was generated from Treasury or Finance?

Mr Learmonth: It depends what you are talking about. If you mean the submission, no, it was generated by the minister for health.

Senator FIERRAVANTI-WELLS: Was it discussed with Treasury and Finance beforehand?

Mr Learmonth: I am not sure what you are referring to, Senator—the submission?

Senator FIERRAVANTI-WELLS: Was there a discussion between the Department of Health and Ageing and Treasury or Finance in relation to potential savings in relation to these listings?

Mr Learmonth: All cabinet submissions involve a process of consultation with relevant agencies, particularly central agencies.

Mr Martine: We would have been talking to health at the time about the costings. Like all submissions, department of finance, Treasury and a number of other departments would have provided comments to be included in the submission.

Senator FIERRAVANTI-WELLS: Who did you consult with? Did you consult with the PBAC?

Mr Martine: No. We normally would not have talked directly with the PBAC. Most of our discussions would have been with the department of health at that time.

Senator FIERRAVANTI-WELLS: I am not asking would they have been; I am asking did you.

Mr Martine: We did not talk to the PBAC in February and we spoke to the department of health.

Senator FIERRAVANTI-WELLS: Did you talk to the Consumer Health Forum?

Mr Martine: No.

Senator FIERRAVANTI-WELLS: Did you talk with Medicines Australia?

Mr Martine: No.

Senator FIERRAVANTI-WELLS: So you had no consultation with anybody in relation to this submission?

Mr Martine: For the February submission that is correct.

Senator FIERRAVANTI-WELLS: Can you tell me what the definition is of 'medicines that treat serious or life-threatening conditions where there are no alternative treatments on the PBS'?

Mr Learmonth: It is a statement of principle the government has made. These are questions of judgment for the government under the circumstances and based on the facts.

Senator FIERRAVANTI-WELLS: Is there a piece of paper that gives us a definition? This appears to be your new criteria, so is there somewhere a bit of paper that defines what this is?

Mr Learmonth: There are no formal criteria. This is a judgment made by the government at the time.

Senator FIERRAVANTI-WELLS: So the cabinet will now sit in judgment on what it considers to be medicines that treat serious or life-threatening conditions where there are no alternatives on the PBS. Is that what you are saying?

Mr Learmonth: It has always been the case that cabinet makes decisions on which medicines should be listed and which should not.

Senator FIERRAVANTI-WELLS: Cabinet has defined what is a medicine that treats serious or life-threatening conditions. Is that the situation? I am trying to get to the definition, which appears to be the new criteria by which listings are occurring. I am trying to find where that definition is, what the criteria are, and in their absence, whether that means that cabinet at each sitting where there are PBS considerations, depending on how it feels on that particular day, will define medicines that treat serious or life-threatening conditions where there are no alternatives.

Mr Learmonth: I have already said, and we have explained before, that there are no formal criteria or definition. These things are matters for judgment by the government on the basis of the facts before them.

Senator FIERRAVANTI-WELLS: How do you decide that?

Mr Learmonth: Clearly the government does, Senator.

Senator FIERRAVANTI-WELLS: For a government that cannot get—

Senator POLLEY: It always has. It is not new.

Senator FIERRAVANTI-WELLS: Given that Minister Roxon has listed medicines and vaccines since the original deferral, have the criteria then changed as a consequence? In February there were some criteria that you were using. Since that original deferral Minister Roxon has obviously changed the criteria, because previously—

Mr Learmonth: I am wondering why you would say that. There are no criteria. That is why I am wondering why you would say they have changed.

Senator FIERRAVANTI-WELLS: Isn't that the problem? How are you deciding? Is it just that a decision is made depending on what time of the day it is or how cabinet feels on a particular day?

Mr Learmonth: No. The government has been clear that it has based its judgment on certain key facts about or attributes of the medicine—the nature of the disease that is being treated, its severity, whether there are alternative therapies available and so on. There is a set of information that is available to government—quite comprehensive information in that regard which comes out of the PBAC public summary documents that it bases each judgment on. Senator, if where you were going with the question was that there have been two medicines that have been previously deferred and subsequently listed, one case—I think it was the Prevnar vaccine catch-up program—as the minister said right at the start, in February, was something that was reconsidered subsequently. It was reconsidered in the budget context and the government made a decision to fund it consistent, again, with the minister saying that if these things were deferred they would be considered in future as circumstances permit.

Senator FIERRAVANTI-WELLS: In that case cabinet deferred and then the minister made a decision herself, without referral back to cabinet.

Mr Learmonth: No. As I said, that particular vaccine was funded in the budget context, which is obviously a government decision. The other one that you might be alluding to was Duodart, which was the subject of a subsequent government decision to list it following review of its costings.

Senator FIERRAVANTI-WELLS: Was it simply that a bit more money became available and as more moneys become available we are going to juggle and vary these deferrals? Is that what could happen?

Mr Learmonth: The minister has made clear that one of the reasons for the deferral was to prioritise in a context of fiscal challenge and that medicines that were deferred would be reconsidered as circumstances permitted.

Senator FIERRAVANTI-WELLS: Can I just come back to my previous questioning about this definition. Are you saying to me that there is no administrative document in existence that defines medicines that treat serious or life-threatening conditions where there is no alternative treatment on the PBS? Are you saying that there is no administrative document in existence that gives us that definition?

Mr Learmonth: There are no criteria in any form by which cabinet makes these decisions—in any form.

Senator FIERRAVANTI-WELLS: I asked you whether there was any written document.

Mr Learmonth: No, Senator, there is not.

Senator FIERRAVANTI-WELLS: In any form, categorically?

Mr Learmonth: Categorically. It is the government's decision making as to what is deferred.

Senator FIERRAVANTI-WELLS: If something falls off the back of a truck—

Mr Learmonth: 'In any form' is inclusive of written, Senator.

Senator FIERRAVANTI-WELLS: That is very good, Mr Learmonth. I will hold you to that if something does fall off the back of a truck. You made comments, and it is also on page 13 of your submission, that seem to be saying that things are still as normal and we have got pharmaceutical companies still putting up submissions to the PBAC. But surely, Mr Learmonth, that is part of a process that has now been ongoing, in some cases, for quite a long period of time. So, despite what the pharmaceutical companies said to us the other day to the effect that this was part of an ongoing process and they are just continuing on with the next step, you are saying that you are taking that to be business as normal.

Mr Learmonth: I am saying a number of things in relation to the assertion that this introduces such uncertainty that there will be a significant impact on drug companies' decisions to bring things to the Australian market. I think John Latham was quoted on Thursday's hearing as saying that that proposition was rubbish. I further note that the level of risk here needs to be put in context. As I said in my opening statement, the risk to the extent that you can characterise it as risk in making this decision to enter the market is at the PBAC end where over 60 per cent of first-time cost-effective applications are rejected. That is where the significant uncertainty is. The uncertainty, if you want to characterise it as that, represented by deferrals is extremely small in comparison.

Finally, I would say that these are large, sophisticated, multinational companies. They make their investment decisions in a range of markets. They will look at what is going on and they will take a very hard-headed business approach to understanding what the risk is. The principal risk remains the PBAC's consideration and the rigorousness of that process. They will have looked at the pattern of what the government has approved—and it has approved over 150 new medicines and listings this year and it has continued to defer only six—and they will make their judgments accordingly, and I believe they will continue to bring things to market in Australia where they believe they are good products.

CHAIR: You made a point about the number of first-time cost-effectiveness applications rejected by the PBAC. Isn't it also fair to say that around the PBAC process there is not only a longer term understanding of what is expected by the PBAC—and there have been transparency measures in place over the last few years to help that—but also an entire discipline around health economics? It is fair to say that the experts in this, whether they be assessors or applicants and sponsors, are aware of the data challenges they need and are aware of what level of evidence they need to take to the PBAC in order to meet the thresholds that the PBAC quite rightly sets for the expenditure of taxpayers' money. There are no such hurdles with respect to cabinet deferrals, are there?

Mr Learmonth: Firstly, your proposition is broadly correct. Does that always pan out in terms of the behaviour of the companies in so far as they all bring beautifully evidenced, competitively priced product? No. Sometimes they do and they are accepted and other times not. Despite all that transparency and familiarity, we will see products that take seven cycles through the PBAC and take a 70 per cent price drop to actually get through.

CHAIR: The point I am making is that that is the way it is meant to work. The PBAC is supposed to act as the gatekeeper. It quite rightly sets a high hurdle, but there are well understood guidelines and an entire academic discipline around health economics. While I take your point that companies obviously have their own interests at heart—and I will not put words in your mouth—and they may understand that there can be gaming of the system, the point is that the uncertainty created by cabinet level decisions, which you yourself have said there are no written guidelines around, is in fact a new level of uncertainty around which the companies cannot plan. They do not have cabinet threshold departments in their own companies to try to work out which medicines cabinet is going to approve or defer, do they?

Mr Learmonth: Equally, there are no strict guidelines around PBAC approvals. There are guidelines around what a submission needs to look like but there are no, for example, guidelines that specify the incremental cost-effectiveness ratio at which the PBAC will find a medicine cost-effective. There has never been and it allows some judgment by the PBAC.

CHAIR: You are not trying to put to me, are you, that the levels of certainty, information and understanding of the PBAC requirements are in any way comparable to those of the requirements to meet a decision by cabinet to not consider the listing of medicines that have been approved by the PBAC? They are two very different steps. One is based on science and economics and one is based, as various people have stated, on the choice of the cabinet. Is that not true?

Mr Learmonth: There is no formal threshold for either the PBAC or the incremental cost-effectiveness ratio, so there is in some ways a parallel. The real issue, though, is one of risk and uncertainty. That is the proposition. As I said, these companies are very large, sophisticated multinational drug companies. They make sophisticated investment decisions in every market in which they operate. They will be looking at what has come out over the course of this year. They will have seen over 150 medicines listed. They will have seen a very small number, six, continuing to be deferred. They will look at the characteristics of those that have been deferred. They will look at the statements by the government about what the government is focusing on in listing and they will calculate their risk. If they do that I do not believe there will be any significant effect on decent products being brought to market.

CHAIR: You have said there that you do not believe. That is not an assertion that you can provide any form of guarantee on; that is a deduction you have made from the evidence that you have just outlined to us, is it not?

Mr Learmonth: It is a similar assertion from those who oppose the measure.

CHAIR: I was asking for an assessment of what you have said. I take it that you are not trying to compare or consider equivalent the planning and the knowledge around PBAC applications with the knowledge and planning around, and the ability to predict—

Mr Learmonth: I am suggesting that there is uncertainty in both processes and that the companies will calibrate that uncertainty when making their decisions.

CHAIR: This new level of uncertainty, however, is a result of cabinet deferring medicines, is it not?

Mr Learmonth: Yes, it is.

Senator BOYCE: I wanted to follow up on that initial 60 per cent failure and follow up on the chair's comments. How many rounds do we do before you have a 90 per cent pass rate?

Mr Learmonth: I think we would have to take that on notice.

Senator BOYCE: Okay, but as you pointed out, some of them will get up to a seventh application. That would be quite rare, would it not?

Mr Learmonth: Yes, that one would be a standout. That is one of my favourites.

Senator BOYCE: That is a known and assessed risk. I think the concern of the pharmaceutical companies, and I hope you would agree, is that there is a new hurdle that has come into the system.

Mr Learmonth: I would not say 'known and assessed risk'. When you say a 'known risk' they know it exists but, equally, the procedures and judgments of the PBAC are not all perfectly delineated either. There is judgment about what is there.

Senator BOYCE: I appreciate that, but nevertheless it is an environment they have operated in and understand. It is all fairly clearly spelt out; although, as you point out, not every decision is going to be as obvious as people might think.

Mr Learmonth: Yes, but to a point. There are a number of drugs which may never make it on and there are a number of drugs which may take multiple goes through. Notwithstanding that they are familiar, it is by no means without uncertainty—more than half get bounced.

Senator BOYCE: Exactly, but we now have a new and quite different hurdle introduced into the system. It is quite reasonable to say that it is what is certainly disturbing the pharmaceutical companies. You appear to be suggesting that they will develop over time an understanding or some sort of ability to assess the risk of having a drug deferred by cabinet. How is that going to happen?

Mr Learmonth: I think, like anything else, they will have developed their understanding of PBAC, for example, over time by getting experience with the process and seeing what is rejected or accepted at various levels of price and uncertainty, and the incremental cost-effectiveness ratio. They will build a sense of what they think they can get away with to maximise their chances and maximise their profit, having regard to both unit price and time of entry to the market. They make those judgments all the time. In this case, I think they would look at the decisions of government over the last year, which listed an overwhelming majority—96 per cent—of what has come forward. They will look at the statements of the minister in relation to what has been listed and what has not been listed, and they will equally start to calibrate and understand that risk. For example, if they were proposing to bring a medicine to market that was cost-effective that treated a severe or life-threatening illness they would look at what has gone on and imagine that the government might perhaps be more favourable to that proposition than otherwise.

Senator BOYCE: But as you know, not every medicine is there to treat severe or life-threatening illnesses and they are very important to us within our PBS and overall system. What I am trying to get at is: why can't we get to the situation perhaps where, if you are going to insist on going down this rather peculiar track, the pharmaceutical companies have some idea of what the criteria might be before being deferred?

Mr Learmonth: Senator, firstly—

Senator BOYCE: I mean why play a guessing game with it?

Mr Learmonth: not everything comes on as equally important. In most of the cases of drugs that were deferred, they are 'me too' drugs which do not add to health outcomes overall. They may make claims to do so. They merely add cost. As for any evolution of this policy in terms of criteria, that would be a matter for government.

Senator BOYCE: Just going back to the question of risk, a number of the drugs that were deferred were in fact put forward for listing because of an invitation to the companies to do so—is that correct?

Mr Learmonth: I am not sure about a number; I think there was one that—

Senator BOYCE: Two, I think.

Mr Learmonth: you asked us about at estimates last time.

Senator BOYCE: And I thought there were two.

Mr Learmonth: There is only the one, I am advised.

Senator BOYCE: Thank you. Nevertheless, would you think that that would somewhat change your view of the risk profile of that drug being listed if you got a letter saying, 'Please apply to have this drug listed'?

Mr Learmonth: It would be a matter for judgment under the circumstances. I cannot answer a hypothetical about what someone else would think.

Senator BOYCE: So a pharmaceutical company would have no right to think that this had any meaning whatsoever. What would happen if a pharmaceutical company declined that invitation?

Mr Learmonth: That would be a matter for them, Senator.

Senator BOYCE: There would be no repercussions.

Mr Learmonth: It depends on the circumstance. It is a bit abstract. I cannot quite get to your question.

Senator BOYCE: Sorry. The TGA writes—

Mr Learmonth: It depends on the circumstance as to why it was being sought, whether there was a health need, whether there were—

Senator BOYCE: Clinical effectiveness and cost were there reasons involved as far as I understand it.

Mr Learmonth: I think in the one case you are speaking about—there are already a couple of others; I will just try and refresh myself. In the case of Synarel—I think that is the one you asked us about.

Senator BOYCE: That is right.

Mr Learmonth: there are already two alternative drugs on the PBS under the IVF—

Senator BOYCE: Why was the letter written?

Mr Learmonth: Under the IVF GIFT program and that particular one, Synarel, is clinically inferior to ganirelix, which is one of the drugs already listed.

Senator BOYCE: The invitation to apply was a lapse of judgment, was it?

Ms Platona: At the time PBAC wrote to the company the drugs were not available. It took Pfizer 12 months to put the submission to the PBAC. By the time the company—

Senator BOYCE: Is that an unusual length of time?

Mr Learmonth: It depends on individual companies; others were much faster.

Ms Platona: The other company applied earlier.

Senator BOYCE: That is quite a reasonable defence to employ. Why wasn't that ever mentioned before? Just one more question: you have talked here about the fact that only 3.9 per cent of the listed medicines for this year were rejected. At the same time, you have opened your statement by talking about the reliability of this system. What do you think reliable means in terms of the PBS?

Mr Learmonth: I will just refresh what I said.

Senator BOYCE: How many stakeholders can think that reliable means the same thing? I can appreciate that we want that for the Australian public.

Mr Learmonth: My statement in relation to reliable was in relation to drugs that are listed on the PBS and it referred to reliable, timely and affordable access to the drugs which are listed.

Senator BOYCE: But how many stakeholders should be able to rely on that?

Mr Learmonth: All of the population should be able to—

Senator BOYCE: But is the system such that manufacturers and other providers should be able to rely on that as well?

Mr Learmonth: My statement of reliable, timely and affordable was in relation to the drugs which are listed on the PBS. They relate to supply through community pharmas and other methods of distribution under the PBS and its related programs. So, yes, they should be able to rely on them to the extent those programs—

Senator BOYCE: I think the chairman is asking me to—

Senator POLLEY: I just wanted to clarify a couple of points that you made in your opening statement in relation to the drug companies. What has been given in evidence is the suggestion that, because there have been some drugs deferred by cabinet at this time, it puts at risk research and development of pharmaceuticals in this country. Can you just explain your response to those suggestions?

Mr Learmonth: I confess I cannot see the link to research. I think the government regards it as important to attract clinical research to this country in terms of building the intellectual capital of the country, and indeed it has a number of active ways it is doing that, including working through the Pharmaceuticals Industry Council and various programs and initiatives which are being implemented under that. It is a very active part of that agenda and the dialogue with the pharmaceutical industry.

They are quite different decisions, though—having a clinical trial in Australia versus accessing the funded market. Clinical trials are conducted as propositions internationally. As I say, these are large multinational pharmaceutical companies. On the innovative side, they will locate their clinical trials—and they are often multisite clinical trials—in circumstances that most suit them in terms of generating the evidence that they will use to claim reimbursement all around the world in various markets and from various payers. Those will go to a range of things, such as availability of populations, price and clinical infrastructure. They will make a lot of judgments about where they locate trials, having regard to how best and most cost-effectively to generate evidence. That is an entirely separate matter from, having obtained that evidence, how and where they choose to take that evidence and seek reimbursement in particular markets. So I cannot see the link.

Senator POLLEY: Would it be fair to say that the drug companies that appeared before us and gave evidence last week, along with those who make application for their material to be listed on the PBS, are, like any other company in this country, motivated by profit as well?

Mr Learmonth: Of course they are. With all their decisions, whether it be about where to locate clinical trials or how to access reimbursement in various markets, they have a duty to their shareholders to maximise their revenue and their profit. They make decisions on the nature of their approach to market and the timing of that

approach to market and the generation of evidence for their payers in a way that will maximise their returns to shareholders. That is their obligation.

Senator POLLEY: In relation to cabinet's processes of making decisions, would it be fair to say that nothing has changed under this government from cabinets under the Howard government or ones before in relation to drugs coming before them to be listed? They take the recommendations of the PBAC into context and then make a decision. Has the process changed?

Mr Learmonth: Not in the sense that it has always been the government's responsibility to take decisions on which drugs are listed on the PBS and to consider the PBAC's recommendations. I do not think there has ever been any advisory committee for any government whose recommendations have always been automatically accepted by government. Certainly in the case of the PBAC it has always been the case that government has considered the recommendations, and certainly in the past there have been occasions when government has chosen not to accept those recommendations.

Senator POLLEY: Are you able to table any document, any written assessment, on the criteria that the previous governments have made in relation to cabinet decisions on drugs being placed on the PBS?

Mr Learmonth: I am not aware that there have ever been any criteria about acceptance or rejection. In the case of previously rejected recommendations of the PBS, the government of the day made a number of statements as to why they were doing so, but I am not aware of any criteria.

Senator POLLEY: In your opening statement you named a couple of drugs that had been not accepted by the then government. Could you outline to the committee the justification that the then government provided for not listing Viagra and any other drugs that were delisted.

Mr Learmonth: I will mention the two best-known examples of rejection of advice. The first was in 1994. The listing of Nicabate nicotine patches on the PBS was recommended by the PBAC in their May 1994 meeting. The then government did not agree to the listing of patches under the PBS, on the grounds that smoking-cessation programs were a state responsibility. In 2002, the PBAC recommended Viagra be PBS-listed for certain groups of patients with neurogenic conditions that led to erectile dysfunction, such as multiple sclerosis. The government rejected the recommendation in relation to Viagra and then also decided it would not be appropriate to continue to subsidise Caverject, which was already on the PBS for erectile dysfunction, and it was delisted. The media release then issued made reference to increasing demands on the PBS and said that funding for these things should not be a priority.

Senator POLLEY: So it is just clear evidence that nothing has changed in terms of the process—that the PBAC make recommendations based on their criteria and that is presented to the government and then of course the government of the day makes the final decision about what does or does not get included in the PBS at that time?

Mr Learmonth: That is correct.

Senator POLLEY: There were some statements made during the course of our hearing that the memorandum of understanding has been breached by the government by deferring these medications. Can you give us your view as to whether or not you agree with those comments and, if so, what clause has been breached?

Mr Learmonth: Certainly. I think—and I would appreciate your guidance if this is not so—there are probably two main areas where they are suggesting the MOU has been breached. One is in relation to cabinet processes and timing. It is clearly not the case that the MOU has been breached. The timetables relate to consideration. Perhaps I can read it to you; it is clause 29:

> For those submissions required to be approved by Cabinet, the Commonwealth will use its best endeavours to implement a maximum time frame of six months for consideration and decision by Cabinet. The six months will commence from the date of notification by the Department of Health and Ageing to the sponsor that pricing is agreed.

In this particular undertaking, since the MOU came into effect, the government has consistently met or bettered this timetable. Two of the last high-cost listings were considered by cabinet within one month of pricing being agreed, which I think is a record.

The other claim about the MOU is this notion of the risk and uncertainty that comes from it. As I was saying in my opening statement, why the industry was prepared to engage in discussion and negotiate the MOU—their underlying motivation—is very different from the intent of the MOU itself, which is a negotiated document in context. Undoubtedly, they sought to enter into discussions to get better certainty for their market and, in our case, to get better sustainability. The intent of the MOU, though, reflected a specific set of things that the government and the industry agreed on. The intent of the MOU is no secret. It is spelt out in clause 3 and the intent is for price certainty. Clause 3 says:

Both parties intend that the MOU will promote the efficiency and sustainability of the PBS and support, by the provision of a stable pricing policy environment, a viable and responsible medicines industry …

The MOU in the next clause, clause 4, goes on, to avoid any doubt, to explain exactly what the intent is related to with the MOU by defining 'price-related'. It says:

The Commonwealth undertakes not to implement new policy to generate price-related savings from the PBS during the period of the agreement, that is, measures that would change the ex-manufacturer price of particular medicines, other than that reflected by this MOU.

So, whatever the underlying motivation was to talk, the intent of the MOU was to provide pricing stability—nothing else.

Senator POLLEY: The PBAC considers obviously the cost effectiveness of medicines, but, to your knowledge, does it take into account the wider health portfolio priorities when making its recommendations?

Mr Learmonth: No, it cannot. It has always been the province of governments' ministers to make those judgments.

Senator POLLEY: In your opening statement, I believe that you said that projected growth going forward with our estimates is 67 per cent of the PBS. Can you explain to us why it is continuing to grow at such a rate?

Mr Learmonth: Certainly, Senator. The two easy drivers are demographics—population change and ageing. But the biggest one of all, as with most of health, is the cost of medical technology: essentially, new medicines being listed. This year, over 150 have been listed at a cost of nearly $850 million and six continue to be deferred. That is the ongoing pressure of the PBS when you are listing new medicines.

Senator POLLEY: So for instance, since 1 January this year, can you outline to us the high-cost listings that have been agreed to by the government and the conditions that are treated by those medications?

Mr Learmonth: From 1 January, Senator?

Senator POLLEY: Yes, in the last six months.

Mr Learmonth: There have been a large number, and I will go through the more significant ones. There was—and this is my pronunciation test—

Senator POLLEY: Rather you than me.

Mr Learmonth: My boss, indeed, has some sport with this pretty regularly. There is: eculizumab, or Soliris, for paroxysmal nocturnal hemoglobinuria, and that was $136 million; azacitidine, or Vidaza, for leukaemia, $124 million; Avodart, or dutasteride, for enlarged prostates, $77 million—these are five-year expenditures—nicotine patches, an extension for smoking cessation, $54.5 million; varenicline, or Champix, for smoking cessation, another $49 million; romiplostim, or Nplate, for a rare blood disorder, $73 million; levodopa with carbidopa, or Duodopa, for Parkinson's disease, $49 million; fingolimod, or Gilenya, for multiple sclerosis, and that is not a published figure, I am sorry, Senator; cetuximab, or Ertibux, for colorectal cancer, and that is not a published figure either; and Prevenar 13 for pneumococcal vaccination, $40 million. They are examples of some of the more significant ones that have been listed, Senator.

Senator POLLEY: Do you have a total amount for those drugs listed since 1 January 2011 for the PBS?

Mr Learmonth: From 1 January 2011 to 31 July 2011, 124 medicines were listed to a value of $561 million and a further 33 were listed later in 2011 at an additional value of $288 million. So it is about $848.6 million over five years.

Senator POLLEY: In terms of the PBS, would this be the fastest-growing major program of the health portfolio? Would I be correct in making that assessment of the PBS?

Mr Learmonth: I would have to think about that. Certainly, it is amongst the fastest, and my colleagues might have a better handle on that.

Mr De Carvalho: I think that is correct, Senator, of the high-growth programs of a similar size or magnitude. The ones that are relevant in terms of magnitude are the PBS, the MBS, aged care and PHI. They are all growing at a rate higher than the government's target in terms of two per cent real growth in funding overall. But I think that it is fairly safe to say that the PBS is probably the fastest growing of those.

Mr Learmonth: It is also from a very large base. It is $9 billion a year from a high growth rate on a high base. It has a very high fiscal impact.

Mr Martine: The other important point to note is that the figures quoted by Mr Learmonth earlier about the growth in the PBS looking forward do not include new listings to the PBS, so the extent that governments agreed to list new drugs will add to those figures of six to seven per cent growth.

Senator POLLEY: In evidence that was given last week there were some assertions made that, because of the process of cabinet decision making—which we have already established has not changed from the previous government—that there is going to be excessive lobbying by interest groups, including drug companies and the public, to get drugs listed. Have you got a view on that?

Mr Learmonth: It is hard to speculate. Ultimately, it remains the case that the PBAC process goes on. Any drug or medicine that the government lists on the PBS must be recommended by the PBAC. That remains the hurdle. That has not stopped companies in the past lobbying. I am sure that they will continue to do so in the future.

Senator POLLEY: In relation to the deferrals of drugs that have brought about this inquiry, there was some discussion by the drug companies that in fact these were better alternatives to those currently listed on the PBS. Does the department have a view on those statements?

Mr Learmonth: The PBAC has a view. It is fair to say in respect to most of these drugs deferred that there alternatives and that—while I stand to be corrected—even the companies did not claim superiority over those alternatives. The PBAC found no evidence of superiority. There were a number of benefits claimed by a number of companies in the hearings last week, but in relation to those mentioned in my opening statement there was no evidence produced to the PBAC.

Senator POLLEY: From the department's point of view, has there been any undermining of the PBAC's authority in terms of the process for making recommendations? Is the criteria that they have always adhered to currently still in force? Is it their job to make recommendations to the government of the day and for the government of the day to determine what will be and will not be listed under the PBS?

Mr Learmonth: Their role has not changed at all. The integrity of that role is intact. In relation to how they feel about it, that might be a question best put to Professor Sansom, who is appearing next.

Senator DI NATALE: Thank you for your submission. The first question I have is in relation to the two precedents that have been cited, the first one being nicotine packages. In your submission you stated that the reason given for not listing nicotine patches was because they were seen to be a state responsibility. Is that correct?

Mr Learmonth: Yes.

Senator DI NATALE: The second precedent was Viagra. The rationale for not listing Viagra was that in fact the condition for which it was listed was not seen to be a condition that should require medications listed on the PBS, and hence the removal of Caverject, which is an alternative form of treatment for impotence. Is that correct?

Mr Learmonth: That is probably going a little further than what I said. I cannot really do other than cite what the then government said in relation to that in their press statement. It was a more general comment that, given the increasing demands on the PBS, funding erectile dysfunction should not be a priority.

Senator DI NATALE: That is right, and therefore the condition for which the drug was listed was not recognised as being a priority. Is that correct?

Mr Learmonth: I could not comment—

Senator DI NATALE: I think that that is what you have just stated.

Mr Learmonth: I could not comment beyond what the government at the time said. You are going more to what underpinned its decision, and I could not—

Senator DI NATALE: I think that we would both agree that the underlying rationale was that erectile dysfunction was not seen as a priority for funding medication, and hence the removal of one form of treatment, Caverject, and the non listing of Viagra.

Mr Learmonth: Certainly the then government said that it would not be a priority in the context of increasing demands.

Senator DI NATALE: We have two examples. One is where a condition was said to be a state responsibility and the other where the underlying condition was not seen to be a priority. Would you not agree that the deferral of six medications with very different rationales for their deferral—that is (a) the conditions are still recognised as being important to be funded; and (b) the government accepts that there is no state responsibility for any of those medications—is a significant departure from previous practice?

Mr Learmonth: I think it is not a departure insofar as that in each case the pressure that we have spoken about on the PBS is significant and in those circumstances the government of the day has made judgements about

what it believes ought to be a priority for funding not just of the PBS but, as a consequence, of course, across the remainder of government activity in health and beyond.

Senator DI NATALE: We have, as I said, the two precedents that have been cited. The rationale for both of those is very different from the rationale for the deferral of the six medications that have been cited for deferral.

Mr Learmonth: That is true insofar as the ones that were previously rejected did not have alternatives. Indeed, the one alternative was removed from the PBS, and the PBS was left with no funded medicine for those particular conditions. In the case of the ones that are deferred now, mostly there is an alternative of equal efficacy available on the PBS.

Senator DI NATALE: I think that does prove the point that it is a significant departure. The second point relates very much to what you have just said. I am not particularly interested in discussing the impact on applicants. I think I share your view that there are a number of factors at work in that space, but I am interested in this question of clinical benefit and the issue around—I think you called them—'me too' medications. I want to talk specifically about two medications. Paliperidone or Invega Sustenna is an injectable form of medication for a psychiatric disorder where compliance is a real issue. With the decreased frequency of injections associated with this medication compared to the existing medication, was compliance considered to be a factor in deciding whether there was any evidence of clinical benefit?

Mr Learmonth: That is perhaps a question better posed to Professor Sansom, but I can say a number of things in relation to this that might help you. In terms of Invega Sustenna there are already two other long acting injections listed on the PBS for patients with schizophrenia. They are risperidone and olanzapine. Paliperidone or Invega Sustenna is not a breakthrough drug. It is the active metabolite of risperidone—Risperdal Consta. Both of those are manufactured by Janssen-Cilag. Paliperidone is simply what the body converts risperidone into when the drug is administered. The PBAC rejected the claim of clinical superiority in clinical practice. The drug was recommended on the basis that it was of similar efficacy and safety to its comparator, long-acting risperidone. I know the manufacturer has made various other claims. They claim that there is a benefit in the reduction of the risk of relapse, but no data or evidence was provided to the PBAC about that to make any judgement. There are claims of longer term benefits; but, again, no data or evidence was provided to the PBAC about that. There are also claims that there are advantages from the drug with quicker stabilisation of patients in the acute setting due to its faster onset of effect to reach therapeutic level—one week versus three weeks. This claim of reduced days of hospitalisation was equally not accepted by the PBAC. There was no evidence about that. The claim that in-patients initiated on Invega Sustenna would be discharged from hospital earlier than patients on risperidone was also not accepted by the Scottish Medicines Consortium, which this year recommended against its use in the national health scheme in Scotland.

Senator DI NATALE: I understand all of that. I suppose my question is whether the issue of compliance is seen to be within the mandate of the PBAC. Perhaps you could take that on notice for me.

Mr Learmonth: I do not need to. It certainly is. Compliance effects are certainly considered as part of the judgement of cost-effectiveness. Again, this is a matter which probably ought to be addressed to Professor Sansom. I think what he might talk about is that, in terms of compliance, there are swings and roundabouts. Part of it is about the interval after which a patient with schizophrenia comes back to their doctor. That regular interaction is important in management as well. Professor Sansom would be the best person to ask those questions.

Senator DI NATALE: I do not think you want to be arguing for more injections for people with psychiatric illnesses as a measure to improve compliance because all the evidence suggests the opposite is true. But we will leave that to Professor Samson. The second question is about oxycodone and naloxone. I think you previously described these medications as 'me too medications'. There is not currently a medication on the market that combines naloxone with an opiate. It is very very clear that this medication provides a different mechanism of action and, therefore, would act very differently on patients who have the very serious problem of opioid induced constipation. The other secondary benefit is associated with diversion of opiates. I am interested in the claim that the PBAC did not base the potential for the reduction in drug abuse on any evidence. There is obviously very clear evidence that with another opiate, buprenorphine, which does have naloxone, there has been reduced diversion and drug abuse with that product. Could you take that on notice if you do not have the information on hand. I understand that there is significant potential for the reduction of opiate abuse in this product.

Mr Learmonth: I can say a couple of things. As you know, the pain management component is a combination drug of oxycodone and naloxone, and opioid induced constipation is the most frequently reported side effect. There are 12 different forms and strength of oxycodone available on the PBS, and the standard clinical treatment on the prescribing of an opioid should be to ensure that the patient also takes a prophylactic laxative in

combination. Clinicians can either direct a patient to purchase that over the counter or they can prescribe one of the laxatives on the PBS. There are numerous laxatives listed on the PBS and 44 different items on the palliative care schedules. The PBAC did not find any evidence that Targin was clinically superior to treatment with an opioid plus an over-the-counter laxative and they did not accept the evidence in relation to a reduced potential for diversion—which I think would only be an issue if it was converted to an injectable form rather than taken in capsule form. Again, Professor Sansom might enlighten you further.

CHAIR: Mr Learmonth, I want to come back to the issue of the MOU. If I heard you correctly, you said the MOU was intended to create some sort of certainty—

Mr Learmonth: No, that is not what I said. What I said was that each of the parties to the MOU undoubtedly came to the table with certain objectives in mind. The industry undoubtedly wanted greater certainty in market access, for example; they can speak to that. For our part, we wanted greater sustainability. There was negotiation and, at the end of the day, a document was produced which both sides agreed to. I am sure it did not do everything that each side wanted but it represented those things which we could agree on. The intent of the MOU is set out in clause (3) and it is extremely clear. It is to provide a stable policy pricing environment.

CHAIR: In the past, the listing of cost-minimised medicines has sometimes lead to additional expenditure and sometimes it has not. It depends on where there has been a change in the patient population. It is true, isn't it, that cost minimised listings can sometimes add cost and sometimes not?

Mr Learmonth: I think that is true as a general proposition.

CHAIR: What we have seen over the course of this year has been language around cost-minimised listings being required to produce savings for health expenditures.

Mr Learmonth: Not that I am aware of.

CHAIR: In an answer to Peter Dutton in the House of Representatives—and the question on notice is No. 279—on Wednesday, 25 May this year Minister Roxon stated:

Additional information taken into account is whether the listing provides expenditure savings …

Mr Learmonth: Again, as you say there are outcomes that may accrue on a medicine which is cost minimised. It may provide additional costs, it may be no cost or it may be a saving. That refers to the fact that, if there is a cost minimised medicine recommended that provides a saving, the government will take it.

CHAIR: I would assume that it would. Whether or not a cost minimised listing has providing a saving has not been a hurdle previously, has it not?

Mr Learmonth: A hurdle to what?

CHAIR: A hurdle to listing, a hurdle to approval to being added to the schedule following PBAC and PBPA, if necessary. Where there has been a cost minimised recommendation by the PBAC, a saving from that listing has not previously been a hurdle for listing on the schedule, has it?

Mr Learmonth: No, it has not been a factor in any listing I am aware of.

Senator FIERRAVANTI-WELLS: On page 6 of the Medicines Australia submission there is reference to the longstanding practice of requiring cabinet approval only for those new medicines with an anticipated budgetary impact of $10 million per annum or more. Indeed, Medicines Australia make reference to this longstanding practice. In footnotes 2 and 3 they refer to a trail of government documents that refer to this longstanding practice. Did cabinet make the decision or did Minister Roxon make the decision to vary this longstanding policy and practice?

Mr Learmonth: It was a government decision.

Senator FIERRAVANTI-WELLS: That was the cabinet decision in February?

Mr Martine: I think I can answer your earlier question. I am advised that the decision was on 21 February.

Senator FIERRAVANTI-WELLS: How long has that longstanding practice existed? For a long time, Mr Learmonth, hasn't it?

Mr Learmonth: Before my time, not that that is long.

Senator FIERRAVANTI-WELLS: That is precisely the point. That is why we are all here. Can you please tell me how long that longstanding practice has existed?

Mr Learmonth: I will take that on notice.

Senator FIERRAVANTI-WELLS: And can you tell me what circumstances have now occurred that warranted a variation of that longstanding practice that has been in existence for years and years?

Mr Learmonth: Again, it is a government decision, but the government decision in relation to the listings in February made clear that it was in the context of the broader fiscal challenge of pressure on the PBS system and the desire for government to properly scrutinise each investment that it might make.

Senator FIERRAVANTI-WELLS: There was a Senate community affairs inquiry into consumer access to the PBS in November 2010. Indeed, this has been looked at by the Productivity Commission. This has been referred to by Medicines Australia. In relation to any responses that the government has made to both the Productivity Commission and the Senate committee report is there now a deviation from any recommendation that the government previously made in relation to either of those reports? Do you see what I am getting at?

Mr Learmonth: Yes, I do.

Senator FIERRAVANTI-WELLS: I would appreciate it if you could look at that because I think, if my memory serves me correctly, that there have been government responses which are now at variance with the policy that the government has now chosen to adopt in relation to its change of position from February 2011.

Mr Learmonth: I am happy to take that on notice. It is of course the government's prerogative to vary its policy from time to time. I would also point out that the point of the calls for cabinet approval thresholds and so on—goodness knows I have had a number of those from industry over the years—is really about timeliness of decision making. What the government has certainly done is achieved on timeliness. It has indeed overachieved in relation to the decisions on listing medicines since the MOU. Whilst perhaps the form of process in relation to thresholds has changed, certainly the government is making very timely decisions, which is in my understanding the motivator behind this push for thresholds.

Senator FIERRAVANTI-WELLS: We have had discussions in various forums about times taken by cabinet. Indeed, at one point it got to about nine months. Do you construe deferral as a decision within the meaning of the MOU and generally?

Mr Learmonth: It is most certainly a decision in relation to that listing.

Senator FIERRAVANTI-WELLS: So deferral in the eyes of this government is a decision?

Mr Learmonth: It is certainly a decision in relation to the listing of a medicine.

Senator FIERRAVANTI-WELLS: How will the process work for reconsideration of these medicines that have been deferred? Will at some stage the government wake up one morning and decide they have a bit more money in the bank and now they can do this? How will the process occur?

Mr Learmonth: That will be a matter for government as the circumstances obtain at the time. Clearly though it has happened on two occasions with respect to two medicines. So the government keeps an eye on those things that were deferred.

Senator FIERRAVANTI-WELLS: You will then at some stage advise the various companies?

Mr Learmonth: If the government makes a different decision about the drugs which have been deferred and that decision is to list then clearly we would need to advise the companies to talk about entry to the PBS.

Senator FIERRAVANTI-WELLS: Can I just ask some questions of Finance?

CHAIR: You have two minutes.

Senator FIERRAVANTI-WELLS: In that case can I ask: what are the actual savings that are going to come out of these medicines that have been deferred?

Mr Learmonth: That actual savings in respect of the ones that have been deferred is cabinet in confidence.

Senator FIERRAVANTI-WELLS: Did Finance coordinate comments with the DoHA submission in February? Did you support the listings?

Mr Martine: I cannot really comment on advice we might have given our minister or cabinet. We certainly gave advice to our minister on the proposals brought forward by the minister for health along with a range of other departments.

Senator FIERRAVANTI-WELLS: So you supported the listings?

Mr Martine: I did not say that. We provided our advice to the minister for finance at the time.

Senator FIERRAVANTI-WELLS: One of the comments that has been made is in relation to the political lottery. This is a point made at page 7 by Medicines Australia. Surely at this stage, in terms of confidence of the public, we have a cabinet that cannot make decisions about school halls and pink batts. What confidence can the Australian public suddenly have that cabinet will be able to make decisions about serious and life-threatening

decisions? Is it not now becoming a political lottery? Cabinet is now sitting in judgment in relation to medicines and which Australians will be helped and which Australians will not be helped with listing of medicines.

Mr Learmonth: Cabinet has always sat in judgment of what is listed on the PBS. Governments of every persuasion have had the obligation and responsibility to make judgments about recommendations from this particular advisory committee. It has ever been thus. In relation to—

Senator FIERRAVANTI-WELLS: That longstanding practice did not apply and there were listings of less than $10 million. I think you need to qualify your answer.

Mr Learmonth: Government in one form or another, whether it be cabinet or the minister exercising the delegation. It has not been the PBAC's role to decide which drugs go on the PBS. They make recommendations and government in some form takes a decision. In relation to the question of lottery, that implies chance. The government has made it fairly clear what it will be focusing on in terms of listings and that is certainly borne out in the over 150 medicines it has listed this year compared to the handful it has deferred.

CHAIR: We have got to move on, Senator Fierravanti-Wells.

Senator McEWEN: I have a couple of questions, one of which goes back to the nicotine patches. Just to clarify, are nicotine patches now available on the PBS?

Mr Learmonth: Yes, that is correct.

Senator McEWEN: When was that decision made?

Ms McNeill: They were listed on 1 February 2011.

Senator McEWEN: That decision to list nicotine patches on the PBS overturned a decision of a previous government, did it?

Mr Learmonth: Strictly, they did not overturn a previous decision. They certainly were not the same applications or submissions, and I am not sure if they were for the same medications. Previously, a recommendation from the PBAC to list nicotine patches was rejected by the then government. In this case a different submission for patches has indeed been agreed to by this government.

Senator McEWEN: How many people does smoking kill in Australia each year?

Mr Learmonth: We will take that on notice, but it would be a large number, I am sure.

Senator McEWEN: I think it is about 15,000 and I think the cost to the Australian economy is over $30 billion a year. I had another question, but I am not sure if it was covered in your opening statement. There have been claims during this inquiry about the destruction of imported pharmaceutical stocks when they reach their expiration dates. The allegation is that that may occur as a result of the deferral of some listings on the PBS. Do you have any comments about that? I think the claim was made by Mundipharma.

Mr Learmonth: There are a number of things. Firstly, there is no requirement to have stock in country when a decision is made; there is only a requirement for companies to say they will have stock available at the time of listing. It is entirely up to the company how they manage that risk. Secondly, these are multinational companies operating multinational supply chains to multiple markets around the world. Access to those markets happens in different ways and at different times, and they juggle their supply chains accordingly. Finally, there are other markets, even within Australia, where medicines can be sold—whether it is on the private market or the state hospital system. I am certainly aware of drugs that are sold on those markets when they are not on the PBS. It is up to the company to manage the risk in the context of managing a global supply chain and global market access.

Senator McEWEN: As far as you are concerned, there is no imminent requirement for the destruction of drugs that are about to expire?

Mr Learmonth: I am not personally aware of anything. Again, the risks in the stocking practices of companies, before government has made a decision, are matters for them to manage. There is no requirement for them to have stock in country before a decision is made.

Senator FIERRAVANTI-WELLS: One of the comments that has been made in the Medicines Australia submission is that this move is pushing us towards a two-tiered health system by deferring the listing of new medicines on purely fiscal grounds. We are moving towards a situation where high-income patients can afford better treatments—with drugs like the schizophrenia drugs and others that are not going to be listed on the PBS—as opposed to those who cannot afford those drugs because they are not listed on the PBS. Is this not going in the face of the long-held objective of equity of access, which is part of the objective of the PBS?

Mr Learmonth: I confess that I cannot see how the facts support that conclusion. There were over 150 new medicines listed at a value of approximately $850 million over five years since 1 January this year. Of the

medicines that were deferred, most of those were ones where there are alternatives already on the PBS—so people are not disadvantaged. You mentioned the schizophrenia medicine, Invega Sustenna. I think I have been through and explained fairly clearly that it is a metabolite of something that is already on the PBS from the same company, over which it is not clinically superior. Indeed, there are two other alternatives on the PBS. So I do not accept the conclusion.

Senator FIERRAVANTI-WELLS: Perhaps you might like to tell Ms Ellsum, whose evidence I hope you were listening to the other day in Melbourne. Her condition unfortunately appears to have been dismissed as being of a minor nature by certain comments that have been made by the minister. What do you tell that lady? She gave very powerful evidence that, had it not been for her grandparents, she would not have been able to afford this treatment for her severe sweating. She is a young girl. I will not go through the evidence. I hope you were listening.

Mr Learmonth: I am aware of it, certainly.

Senator FIERRAVANTI-WELLS: It was very powerful evidence. What do you tell that girl when the alternatives for her give her rashes and cause her a lot of distress? There is no alternative for that girl, yet you are telling her, effectively, that she cannot have the injections. She will not be able to afford them and she will have to put up with skin rashes for the rest of her life. There are lots of examples.

CHAIR: Senator Fierravanti-Wells, I encourage you to put a question to Mr Learmonth.

Senator FIERRAVANTI-WELLS: What is your response to that girl's evidence, Mr Learmonth?

Mr Learmonth: All I can say is that that was the decision of government in the case of that particular medicine.

CHAIR: Concerning oxycodone and naloxone, from what you are describing earlier I got the impression that there was not really a great weight placed by the PBAC on their prevention of constipation or lack of complications with respect to the use of laxatives and pain medication and also potential reduction of diversion.

Mr Learmonth: There are two things in relation to the potential for diversion. The PBAC consider the proposition that there was not persuasive evidence in relation to the laxative effect. I can be corrected if I am wrong but I think even the company did not claim any superiority in therapeutic effect over standard oxycodone plus an over-the-counter laxative.

CHAIR: I thank officers for their time today. I believe we have just over a week with respect to answers to the questions you have taken on notice. We will be grateful if we can receive those answers as soon as possible.

Mr Learmonth: We will give you the answers as fast as we can

CHAIR: Thank you.

Proceedings suspended from 10.32 am to 10.46 am

SANSOM, Emeritus Professor, Lloyd Norman, Chair, Pharmaceutical Benefits Advisory Committee

CHAIR: Welcome. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. I invite you to make a short opening statement at the conclusion of which I will invite members of the committee to put questions to you. I would like to note that, after more than a decade of service, this will likely be Professor Sansom's last appearance before a Senate committee as he is retiring from the position in the coming weeks and months.

Prof. Sansom: Good morning. As you will be aware, the PBAC is an independent statutory committee established under the National Health Act to advise the Minister for Health and Ageing which medicines together with any relevant terms and conditions can be considered for listing as a pharmaceutical benefit.

The PBAC is not a statutory authority such as the Reserve Bank or Civil Aviation Authority and does not make the decision regarding the listing of the medicine as a pharmaceutical benefit. This fact seems to be misunderstood in a number of the submissions to the inquiry, which infer that a positive recommendation to the PBAC is or should be binding on government. While the minister cannot list a medicine as a pharmaceutical benefit unless a positive recommendation is received from the PBAC, a positive recommendation allows the minister to consider a medicine for listing as a pharmaceutical benefit. It does not compel a government to give effect to that recommendation.

This process has been in operation since the committee was established in 1953 and has not changed since that time. The PBAC also provides advice on other matters referred to it by the minister as allowed under the act—for example, regarding therapeutic group policies. As is the case with other recommendations from the PBAC, such advice is advisory to the minister. Over the years, there have been instances where the advice of PBAC has not been accepted. You have heard of some of those this morning.

One of the great strengths of the PBAC process is its independence and this has been acknowledged in virtually every submission to this inquiry. This independence relates primarily to the removal of any political or other pressure either real or perceived regarding undue influence on the decision process of the PBAC—that is, each recommendation to the minister is based on the evidence presented and the evaluation of that evidence taking into account other issues which are clearly identified in statements issued by the PBAC after its meetings and its public summary documents.

In making its recommendations, the PBAC takes into account the clinical effectiveness and cost effectiveness of the therapy compared to other medicines or therapies which it will replace in practice. If the medicine is deemed to be no worse than its comparator either in regard to efficacy and toxicity then PBAC will only make a recommendation if the price is no higher than its comparator taking into account issues such as differences in the cost of administration and any costs of managing toxicities. This is referred to as a cost-minimisation approach to which the chair referred this morning. However, as was also identified this morning, this does not necessarily mean that there will be no increase in total cost. If a medicine is deemed to be superior to its comparator in efficacy and/or toxicity, then the incremental benefit is considered in the context of the price requested and an incremental cost-effectiveness ratio is calculated, called an ICER. This is usually expressed, wherever we can, in terms of a cost per quality adjusted life year. That brings every disease back to a common metric.

The PBAC, unlike the equivalent in the United Kingdom, does not use a fixed threshold but considers such matters as the social impact of the disease, the availability of alternatives and the unmet clinical need in making its recommendation. These less quantifiable factors are clearly listed in the guidelines for submissions, issued by the PBAC. The introduction of the publication of the PBAC agenda some six weeks before the meeting, which recently occurred in last 12 months or so, has enhanced the ability of consumers and others to comment to the PBAC on these matters. After each meeting, the PBAC publishes public summary documents. These documents, which are based on the minutes of the PBAC meetings, provide a summary of the clinical and economic data presented to the PBAC, together with its reasons and recommendations. These will include statements regarding the comparator used in the evaluation, together with comments regarding the relative effectiveness and toxicity of the medicine compared to its comparator.

For example, the PBAC might say that the PBAC accepted that the submissions claim that drug A was not inferior to drug B in terms of both effectiveness and safety and accepted the therapeutic equivalents of drug A versus drug B based on clinical trials presented in the submission. This means that on a population basis the same therapeutic response would be expected from either product. This is not evidence that the product will have the same response at every medication-naive patient or in those who have had an inadequate response or failed response to one of the other products. Under these circumstances the comparison between the two products

becomes irrelevant and the population of interest is one in whom one of the drugs has failed. That is, the evaluation has a completely different context. Second-line therapy is different to first-line therapy in both outcome and cost effectiveness.

The public summary documents will also contain statements where applicable regarding whether the medicine has the potential to fulfil an unmet clinical need or whether it is superior to its comparator. For example, the PBAC might state—and this is taken directly from an example of a public summary document—that the PBAC accepted that drug A was superior in terms of comparative effectiveness and had a similar safety profile to drug B. Against this backdrop, with regard to the issue of deferrals, which is a post PBAC matter and is not an issue for the PBAC, the PBAC believes this is a policy issue for the government. If the PBAC had been asked to endorse or otherwise the policy, it could have been construed as compromising the independence of the PBAC, which underpins its very fabric and for which it has international acceptance and recognition. However, the PBAC does believe that it is appropriate for any minister of health and ageing to whom it may report to consider its recommendations, taking into account the issue of opportunity costs. While medicines are an important element of any health policy system, and that is clearly evident, there are many other elements which demand increasing resource allocation in line with increasing demand and health services, both indirect and direct. I am happy to answer any questions relating to the PBAC.

CHAIR: Thank you.

Senator FIERRAVANTI-WELLS: Professor, thank you for your evidence. When did you first hear about the government's decision to defer the PBAC's recommendations?

Prof. Sansom: I received an email from the first assistant secretary at 5 pm on 24 February. That was an obvious question, so I went to my emails to find that out. The issue was that the minister was to write a letter to the chairs of PBAC, ATAGI, which is the immunisation advisory group, and the pricing authority regarding the decision to defer listings. The letter was not available at that time, so I was sent a letter by the first assistant secretary saying the minister's office had agreed that the following statement would be made available to me. That was on 24 February. I then circulated that to PBAC members at 6.10 that night. About three days later I got a formal letter from the minister, signed by the minister, saying the same thing—that there was to be a referral and the reasons for that referral, and, again, I circulated and tabled that letter at the PBAC meeting in March.

Senator FIERRAVANTI-WELLS: Is that letter available to be tabled here?

Prof. Sansom: That is an issue. I do not know what the process is. This is a letter from the minister to me as the chairman of the PBAC.

CHAIR: If you are happy to table it, Professor Sansom, then—

Prof. Sansom: I do not have it with me.

CHAIR: Unless it is subject to cabinet confidentiality—

Prof. Sansom: I would have to check. I would have to seek advice about that. If it is not, then, yes, I would be happy to table that letter.

CHAIR: The only thing that I would say, Professor Sansom, is that the decision is effectively yours. If it is not a cabinet document, then it would not be subject to a confidentiality issue. I would counsel people against necessarily always taking advice from the government, which does not have the same interest in transparency.

Prof. Sansom: I will take advice across a broad spectrum.

Senator FIERRAVANTI-WELLS: Was the PBAC asked for advice on which medicines and vaccines could be deferred?

Prof. Sansom: No.

Senator FIERRAVANTI-WELLS: Were the deferrals discussed at the July PBAC meeting?

Prof. Sansom: Sorry, was the issue—

Senator FIERRAVANTI-WELLS: Was the issue of the deferrals discussed at the PBAC meeting?

Prof. Sansom: The issue was discussed in a closed session of the PBAC in March of this year. The letter to me from the minister was tabled and the committee discussed that letter.

Senator BOYCE: What do you mean by a closed session?

Prof. Sansom: I removed all departmental officers and advisers from the room and the PBAC met in camera.

Senator FIERRAVANTI-WELLS: Did the PBAC resolve—

Prof. Sansom: The PBAC affirmed the last paragraph that I gave you, which is that it is prerogative of the minister. The decision to list is a responsibility of the government. It is our responsibility to advise and to make recommendations. Regarding the last sentence with respect to opportunity costs, the committee deemed that considering opportunity costs was also an appropriate thing for any government to do in taking recommendations and makings its final deliberations.

Senator FIERRAVANTI-WELLS: Have you been provided with any advice from the minister or from the department on the revised cost minimisation policy in light of the recent decision to defer listings on the grounds of cost minimisation?

Prof. Sansom: No.

Senator FIERRAVANTI-WELLS: No? You may have heard my questioning of Mr Learmonth earlier about what appears to be the government's 'criteria' that it will be concentrating on the listing of medicines that treat serious or life-threatening conditions where there are no alternative treatments on the PBS. Professor, do you have a view about that?

Prof. Sansom: The PBAC makes recommendations to government. We take into account certain issues in coming to our recommendations. They are explicit within the guidelines of the PBAC.

Senator FIERRAVANTI-WELLS: Your guidelines state—and correct me if I am wrong—that you must be satisfied that the new medicine or vaccine is needed for the prevention or treatment of significant medical conditions not already covered or inadequately covered by drugs in the existing list and is of acceptable cost effectiveness.

Prof. Sansom: If you read the full context, it will say, 'if they wish a price increase'. That does not relate necessarily to cost minimisation.

Senator FIERRAVANTI-WELLS: So you have your guidelines that you will follow, and there has been no variation there.

Prof. Sansom: The consistency of PBAC deliberations is critical to its credibility.

Senator FIERRAVANTI-WELLS: But the government could makes it decisions on criteria that are totally outside what you may consider.

Prof. Sansom: That is a government prerogative.

Senator FIERRAVANTI-WELLS: I am not questioning that. I am simply stating that you make your decision based on your defined criteria and what the government then does is up to them. If it decides to make a decision on how it feels on a particular day is a matter ultimately for the government.

Prof. Sansom: Yes.

Senator FIERRAVANTI-WELLS: I want to ask about hyperhidrosis. Can you talk about the drug treatment for that in particular? I am not sure whether you heard the evidence—

Prof. Sansom: I have read the evidence. All I can say is that the PBAC made a positive recommendation regarding that drug to the government and to the minister with certain conditions, such that the listing only relates to hyperhidrosis axilla—under the arm—so the drug is not relevant to issues to do with hands and feet that some of these people talk about. But the PBAC clearly identified excessive sweating, hyperhidrosis of the axilla, under certain conditions. It had to be second line—people had to try other things first. That recommendation to the government still stands.

Senator FIERRAVANTI-WELLS: So it is wrong to say that this drug does have an alternative.

Prof. Sansom: The drug has an alternative. The drug has both therapeutic and surgical interventions. The PBAC believed that botox had a place in the therapeutic regimen of excessive sweating under certain conditions. That was a condition of the recommendation to the minister.

Senator FIERRAVANTI-WELLS: And it was a cost-effective alternative.

Prof. Sansom: It was deemed to be cost-effective, yes. That recommendation is in the public domain.

Senator BOYCE: I have a couple of questions along the same lines in regard to Synarel. We were given the impression this morning that Synarel—

Prof. Sansom: I work in drug names, not trade names, so I have to find where you are at. That is nafarelin.

Senator BOYCE: We were given the impression this morning that Synarel was not an alternative but was simply an add-on existing medicine. Is it not the case that Synarel is an 'agonist', not an 'antagonist'? In the PBAC's view, is it a 'me too' medicine'?

Prof. Sansom: It is an interesting history if you want to go back and look at the whole area. This group of drugs, the GnRH analogs, are the only drugs in the IVF gift program that are not funded. The PBAC took affirmative action. We got a submission from one company for an antagonist and we agreed with that. Under due process, we then wrote to the other companies. We did not write to them because they had a right to have this extended to them because this was an essential drug; this was due process. We commonly do that; it is appropriate that we do that. We wrote to Merck Serono in regard to cetrorelix and we wrote to Pfizer in regard to nafarelin. Ganirelix, which is also an antagonist, came in quite quickly, and we recommended that. Twelve months later, Centralix came in and we looked at that.

Quite interestingly, when we had clinical evidence presented at the hearing by the IVF specialist, it was fascinating to look at the utilisation of agonist versus antagonist around Australia. In some IVF units in this country it is 100 per cent agonist and zero per cent antagonist; in others, it can be completely the opposite. This is about the clinician's preference; it is not about anything else. Also, with nafarelin we did not get the same price as the antagonists because this particular drug has a higher instance of what we call ovarian hyperstimulation syndrome—and the cost of managing that issue was taken off the price. So there are alternatives in terms of antagonists, and some IVF units will only use antagonists. I do not know why.

There was also evidence presented to us at that hearing that a number of women do access nafarelin under the PBS at the moment because it is listed for endometriosis—and a number of women with infertility have endometriosis. So there is a percentage of people who, I suppose, are being denied; but, depending on which clinician and which IVF unit you speak to, you might get completely different answers. In terms of us inviting them, which I saw in some of the transcripts I read, this was due process from PBAC; this was not us saying, 'Please, please come in.' But we do do that at times—trust me—particularly with certain minority groups, including Aborigines and Torres Strait Islanders. We have affirmative action. We say to companies, 'Please put in a submission to us because we want that drug for that group of population.' But, in this case, that was not the case; it was purely due process.

Senator FIERRAVANTI-WELLS: Prof Sansom, you may have heard the evidence earlier about the longstanding policy and practice of requiring cabinet approval only for those new medicines with an anticipated budgetary impact of $10 million per annum or more. How many PBAC recommendations have not been followed by the minister in relation to those of less than $10 million and those over $10 million? You can take that on notice.

Prof. Sansom: I would have to take that on notice. I think the issue is that there is no question that the number of deferrals in this period of time is greater than in my experience as PBAC chair. It may be a departure of outcome; it is not necessarily a departure in process.

Senator FIERRAVANTI-WELLS: Sorry, could you just go back.

Prof. Sansom: It may be a departure in outcome. In other words, in the last six months it has been more deferred. But as far as PBAC processes are concerned that has been consistent.

Senator FIERRAVANTI-WELLS: In relation to the Janssen product.

Prof. Sansom: Paliperidone, Invega.

Senator FIERRAVANTI-WELLS: The Sustenna. In their submission they set out, and evidence was given the other day, the cost of the listing as opposed to the estimated savings from avoidable hospitalisations and those sorts of matters. Are they the sorts of things that are taken into account as part of your criteria?

Prof. Sansom: Absolutely. Cost offsets, hospitalisations, different hospital visits and clinical visits are all taken into consideration. This drug was given a price premium over Risperidone on the basis of one additional administration because it is once a month as opposed to once a fortnight. The data presented to PBAC for this drug showed it to be no worse. We did not accept the hospitalisation rates. The company came in with a cost-effectiveness argument about all types of things, which we rejected. We offered a cost-minimisation approach where the cost of Sustenna was equal to the cost of Risperdal Consta plus the cost of a visit and administration cost. So they did get a higher price, equivalent to one, because there was a saving, if you like, of one visit. But in terms of clinical outcome there was no data which was acceptable to the PBAC, even including compliance.

Compliance is an interesting issue, Senator, because it is much more convoluted, as you would know, than the frequency of administration. This drug caused significantly more pain on administration than do others. That could be a factor. There are a lot of factors which impact on compliance particularly in patients in mental health. PBAC acknowledges that there may be an advantage. But in terms of compliance, which is the issue that has been raised, PBAC acknowledges compliance but only in the context of a health gain, not that I think compliance

would be better. If compliance is better you would expect to see an improvement in the health outcome. If you get the improvement in the health outcome that is what we will pay for.

Senator FIERRAVANTI-WELLS: I will let Senator Polley have a turn now. I would like a chance at the end, if I may, as I am looking for my place.

Senator POLLEY: Professor Sansom, can I also place on record my appreciation of the work that you have done during your time as chair. I think it would be useful for the committee and also for people who have a great interest in this issue if you could outline the process that the PBAC goes through to list a drug for recommendation to a government.

Prof. Sansom: Senator, the guidelines for submissions to PBAC is a very comprehensive document. We receive submissions from industry in the vast majority of cases. Every now and then we will get a submission from a health professional but the vast majority of the submissions received by PBAC are from sponsors, that is drug companies. Those submissions have to be in accordance with our guidelines. In other words it requires certain evidence and the PBAC.

That submission is then evaluated by independent evaluation groups around Australia and the PBAC receives an evaluation report. Some of these are very extensive of about 150 or 200 pages. They are critical evaluations of the submission. That evaluation goes to the sponsor and it also goes to our economic subcommittee. They look at it and make a report to the PBAC. That report also goes to the sponsor. Then it comes back to the PBAC.

So the PBAC has a submission, volumes, it has an evaluation report, it has the report from the economic subcommittee, it has the report from the drug utilisation subcommittee, it has feedback from the industry in response to all of those and then the whole thing is considered. That looks at the clinical efficacy, as I have said—does the drug do what it says; how certain we are of that; how uncertain we are of that. It then extrapolates into the economics and some of that will be extrapolated by very complex economic models. Then PBAC will weigh up all the evidence and the committee of 18 members will then make the judgment call. It is tough being a member of the PBAC. The easiest thing for PBAC members is to say yes without restrictions. That is the easy option and that is not an option which PBAC considers appropriate. The process is, I believe, very rigorous. After PBAC meetings we publish public summary documents. I meet with companies who have failed after the meetings and go through why it was rejected and what they have to do to amend that. So it is a very rigorous process and I think it has stood up internationally as one of the premium drug evaluation units in the world.

Senator POLLEY: Thank you for that observation. Can you then confirm for me that there has been no change in the last four years to the way in which the PBAC makes recommendations, no criteria have changed under this government and your independence is still sacrosanct?

Prof. Sansom: Absolutely and I can assure you it is jealously guarded by me as chair on behalf of the committee.

Senator POLLEY: So it should be. In your experience, when your committee makes a recommendation, is or is it not within your responsibilities to consider the other programs within the health budget?

Prof. Sansom: No, we do not compare it, say for hypertension, with exercise and diet. That is not our province, unless exercise and diet becomes a standard comparator. In some cases it may be, but in general no. That is why I read the statement in my opening remarks when Senator Fierravanti-Wells asked me what did we discuss. That is what we discussed. It is appropriate for any government to consider opportunity costs within our recommendations. Not to do so we believe would be inappropriate.

Senator POLLEY: In your expert opinion from being on the committee for some considerable time and the drugs that you have evaluated, would it be fair to say that there will always be some patients who will not have access to a particular medication through the PBS?

Prof. Sansom: As I said, it is easy to say yes. Even when PBAC says, 'No, the drug is not cost effective,' we know that there will be patients who may have benefitted from that drug. That pertains to every decision that PBAC makes. Let me put it another way: for any country to go to a purely individualised patient system—that would mean you would make every drug available without any restrictions so you can try as many as you like—the system would be broke in a very short space of time.

Senator POLLEY: In relation to the way the PBAC makes recommendations to the government, you have said on the record here a number of times that it is the prerogative of the government of the day to make that decision.

Prof. Sansom: Absolutely.

Senator POLLEY: Would you recommend any change to that?

Prof. Sansom: No. To do so you would have to comment on a government policy. I have said repeatedly in the last 11 years that while the PBAC starts with a P it does not comment on policy.

Senator POLLEY: In relation to the claims some pharmaceutical companies have made in relation to the deferral of these particular drugs, that it could very well mean that Australians could lose out on some research and development and supply of medications, from your experience do you see that as a likely outcome?

Prof. Sansom: That is highly unlikely I would argue. I think the deputy secretary said that this is a global market. We have a high reputation. We are highly skilled in clinical science. I think companies will make the judgement. This is quite a stable market. Once you get listing, this is a very stable market. I think it is a commercial decision and I do not believe it will have a major impact at all. That is a personal viewpoint; PBAC has not discussed that.

Senator DI NATALE: Professor Samson, I would also like to congratulate you on many years of very distinguished service. I am also very interested in your initial oral presentation, in particular this notion that we have 'me too' medication. Let us look at the example of oxycodone and naloxone. Is it true to say that—where there is no demonstrated benefit comparing one medication with the alternatives—there would be some people who would be better off, who may not respond to oxycodone with a laxative, who would respond to this medication? In other words, the people that respond may be different people.

Prof. Sansom: We gave a positive recommendation, Senator. The trials were conducted that were submitted to us were for oxycodone and naloxone, versus oxycodone. The price that PBAC determined it would start its economic analysis on was less than the company wanted and we said that the price that we would start our economic analysis on was oxycodone plus the cost of laxatives. In other words there was no evidence presented. The only evidence that was presented in terms of the use of laxatives was that there is a huge quality use of medicines with clinicians to improve the prophylactic use of laxatives. Every guideline in Australia recommends it and yet the percentage of patients who are started on long-term opioids and on prophylactic laxatives is not high. We said that it worked. Does naloxone work: yes, it does work. That is why we funded it. If it did not work and was not any better, it would not have been funded at all. It has a 20 per cent price premium over oxycodone.

In terms of deferral, the abuse potential that you referred to was acknowledged by PBS and no data was presented. You also mentioned buprenorphine with naloxone. The advice given to me was that the reduction in abuse potential of that is not as much as we would have hoped for. It might have some benefit. There was no evidence presented that it was going to be absolute and there was no evidence presented that we could quantify, and if you read the public summary document it says that the PBS acknowledges it, but was not able to quantify or value it in terms of a dollar value.

In terms of diversion of opioids, that is a huge issue for PBAC. We have just held a stakeholder meeting of all consumer groups, clinical groups and drug companies about the issue of opioid use in this country. So PBAC does have an interest in it, and in terms of this particular drug there was no evidence presented that it was any better. But we made a recommendation and the recommendation stands.

Senator DI NATALE: In your view, do you think that it represents a significant opportunity to reduce the abuse—just to be clear—of oxycodone, also known as 'hillbilly heroin' injected quite frequently as a substitute for heroin? Is there significant potential to be made in terms of reducing the diversion of oxycodone?

Prof. Sansom: I think there is a potential for it to do so. As you are well aware from your own background, it is very hard to keep 10 steps ahead in this area. As a matter of pharmacological theory, if you like, the answer is yes, but that said, the PBAC was not provided with any data. If we were provided with that kind of data, would we take that into account so that we could quantify and put a figure on it: the answer is yes. In this case, we could not. The PBAC minutes clearly acknowledged that there was a potential advantage for this product.

Senator DI NATALE: I suppose the question for me then is: is that a failure of the applicant in terms of presenting data that might have supported their case?

Prof. Sansom: Yes. Basically, if they wished to quantify that with respect to a cost, that should have been in the submission to an extent that the data was credible and was based on evidence and not anecdote. In this area, as you know, anecdotes flow very easily and very quickly. That is not the basis for making decisions. But as I said, we are concerned about the use of opioids, and if that is the case we had better ban all the other opioids on the PBS list, and I do not think that anyone would suggest that.

Senator DI NATALE: This is clearly not a ban. It is actually continuing the use of what is recognised as an opioid that produces significant pain relief but also minimising the risk of diversion.

Prof. Sansom: So does morphine. You could do the same with morphine or fentanyl and you could keep going on and on and on in that area.

Senator DI NATALE: Does the PBAC ever take a proactive step in terms of considering evidence, or is it purely basing its decisions on the evidence provided by the applicants?

Prof. Sansom: We are proactive. We have reviews. We have recently had a review of the biological DMARDs for rheumatoid arthritis. Members around the table will often be aware of evidence but remember that the PBAC cannot use evidence which is germane to its decision without the sponsor being aware of that. So sometimes I will have to defer consideration at a meeting because a member has brought up a new piece of evidence that has just been published which we believe is relevant to the committee's concerns and I will defer the matter to enable the company to respond to that. So we are proactive, yes.

Senator DI NATALE: So, in this case, the evidence was not presented by the applicant?

Prof. Sansom: No.

Senator DI NATALE: What would have been the trigger for the PBAC to say, 'Actually, we think this has significant potential benefit and we are going to—

Prof. Sansom: We would have to go and try to determine whether or not evidence was available. Was there any evidence available, or was it a hypothesis?

Senator DI NATALE: In this case we already have an example where there has been—

Prof. Sansom: Well, it is a hypothesis. You may be familiar with it, but I am not familiar with the literature about this particular product and its abuse potential. I think the words used were that it has 'the potential for abuse'. I am not aware of evidence for that potential. If there is evidence and that evidence is fairly strong, then that would be a thing that the PBAC would take into account and would in fact quantify.

Senator DI NATALE: Thank you.

Senator FIERRAVANTI-WELLS: Professor, the process undertaken here with the PBAC and the framework has been described in various of the submissions as world-leading. But there is a concern that we will now see a politicisation of the process. So, in effect, going back to your previous evidence, the PBAC could make its recommendations based on its guidelines and then, effectively, see that process recommenced, if I could put it that way, because cabinet has a different criterion and will consider it, in effect, de novo. Aren't the fears of politicisation justified?

Prof. Sansom: That is a post PBAC consideration. I have no comment to make. You could say that right across the board, of advisory committees right across the whole spectrum of government. They advise governments, and we have a democracy where governments make decisions.

Senator FIERRAVANTI-WELLS: In that case, can I take you to the submission that was put in by AstraZeneca and the comparison of Symbicort and Seretide. You talked before about evidence in relation to cost and cost-effectiveness. In that submission—do you have a copy of it?

Prof. Sansom: I have a public summary document. And, from memory, the company came in and asked for a cost minimisation against the comparator—no advantage.

Senator FIERRAVANTI-WELLS: Can I just ask: is this the sort of stuff you take into account? They have a table there that looks at the annual cost to patients with chronic obstructive pulmonary disease who are treated with the two drugs respectively which sets out the cost per prescription and cost to patients, and it seems to be more cost-effective in relation to—

Prof. Sansom: No, it is no more cost-effective. The cost-effectiveness is based on the clinical outcome.

Senator FIERRAVANTI-WELLS: But is that the sort of data that you look at as part of your deliberations?

Prof. Sansom: We are required to examine what we call section E, I think, of the submissions, which relate to utilisation. No minister likes what is called fiscal uncertainty. I have been informed of that by every minister with whom I have served. But we will look at that, and that will be taken into account as a part of the deliberations. Then the detailed analyses, of course, about total costings and so on, are post PBAC.

Senator FIERRAVANTI-WELLS: So, again, as to the annual cost to government—and I thank Dr Di Natale for his assistance in relation to dose per metered equivalent—those sorts of annual costs to governments are things that you would take into account, or is that material that would be submitted to you?

Prof. Sansom: There were materials—in that particular case I think you are referring to reduction in copayment.

Senator FIERRAVANTI-WELLS: Yes.

Prof. Sansom: It is nothing to do with the cost-effectiveness of the agent; it is to do with the net cost to government. That has been recognised within—

Senator FIERRAVANTI-WELLS: Yes, but it is all material that is before you, and you just make a ruling one way or the other, and then anything above that, such as annual cost to government, would be something that then the political process would take care of?

Prof. Sansom: We would note there any cost to government. We would note whether or not there was uncertainty within that. For example, that company might say it is $10 million, but if it is likely to be what we call least indications, or situations in which we did not find it to be cost effective, we would say, 'We note that the company says it will be $10 million; however, we believe that's highly uncertain and it could be $50 million or $200 million', which has happened in one case. Our advice to government would then include that there should be a price volume arrangement or risk share arrangement or some other issue with regard to that. That is the way that that will cure issues.

Senator FIERRAVANTI-WELLS: Can I then ask you the reverse: if there is an annual saving to government, do you also—

Prof. Sansom: We would note if the company says there is a saving, and if we believe that is likely to occur we would say that there is likely to be a saving. However, if they say it is a saving and we say, 'Pigs might fly', we would say: 'They asked for a cost saving; however, we believe the company has not acknowledged the following and it is most unlikely that there will be a cost saving.' That is the extent to which we go.

Senator FIERRAVANTI-WELLS: So potentially you have a situation where it could be an annual saving to government—

Prof. Sansom: In certain circumstances it could be, if we are convinced of that.

CHAIR: I look forward to the cabinet minutes, if something says 'pigs might fly', Professor Sansom. On behalf of all of us here, I thank you for your service over more than a decade in that role. It is one of the tougher jobs in the public sector.

Prof. Sansom: Thank you very much. I wish you all the very best.

BRUCE, Mr Andrew, Executive Director, Health Policy and Research, Medicines Australia Ltd

SHAW, Dr Brendan, Chief Executive, Medicines Australia Ltd

[11:26]

CHAIR: I welcome representatives of Medicines Australia. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee has your submission. I invite you to make a short opening statement, at the conclusion of which I will invite members of the committee to put questions to you.

Dr Shaw: Thank you for the opportunity to appear before the committee today. As a representative body for the Australian medicines industry, Medicines Australia is deeply concerned about the Australian government's decision to defer the listing of new medicines on the Pharmaceutical Benefits Scheme; to defer recommended price increases for existing medicines, which affects both innovative and generic companies; and to exercise cabinet veto over the listing of potentially every new medicine.

Today marks five months to the day since cabinet announced the deferral of the listing of a number of medicines on the Pharmaceutical Benefits Scheme. For patients this has meant five months without medicines that would materially improve their lives. Patients suffering from schizophrenia, excessive sweating and chronic pain are all missing out. As more medicines come up for listing, more patients are now anxious that they too will miss out in the future. With cabinet choosing to list only some cost-effective medicines on the PBS, we run the real risk of developing a two-tier health system where the wealthy can afford the most effective and convenient treatment options while the rest have to make do with less effective and less convenient treatments already on the PBS. Medicines Australia's submission to the inquiry and our testimony today are based on one key proposition: the PBS is not broken and until 25 February this year it did not need fixing.

I would like to briefly raise four key issues with you. Firstly, as you will have read in our submission, industry finalised a memorandum of understanding with the Australian government three months prior to the cabinet's announcement about deferrals. Savings from this historic agreement are estimated to be at least $1.9 billion. These savings are yet to flow through the system, and we expect still more savings in addition to these, going forward. The MOU is an example of how policy can be developed and improved through constructive collaboration between government and business. Medicines Australia is proud of its history of working constructively with all sides of politics. The Australian government approached industry, seeking assistance in achieving their fiscal goals. Last year we entered into tough but fruitful negotiations with the government that delivered a minimum of $1.9 billion in savings and a series of other measures to improve the efficiency and sustainability of the PBS. This was achieved with no compromise to patients' access to medicines. Three months later the government made an arbitrary decision, without consulting industry, patients or health professionals. This decision may save in the order of $25 million a year in the short run but, in the long run, will cost the government more money and will limit Australians' access to medicines and potential improvements to their quality of life.

Thirdly, as our submission clearly shows, the growth of the Pharmaceutical Benefits Scheme is at historic lows. Treasury's own projections from last year's *Intergenerational report*, as reproduced on page 27 of our submission, suggest that growth will remain flat, at around 0.7 per cent of GDP until at least 2020. The message we want to leave you with today is that the PBS is a sustainable, well-run program that delivers major benefits to the health of the nation. These benefits run far deeper than a simple reading of the balance sheet by an accountant would suggest.

Fourthly, industry understands the prerogative of government to make spending decisions. However, we also believe that the government should exercise this power judiciously and sparingly, as has happened in the past. This new change where cabinet will now scrutinise all new medicines seeking listing on the PBS and is systematically prepared to veto the listing of new medicines for budgetary reasons is a bad change. The government's own independent expert committee process rigorously analyses medicines for both clinical effectiveness and cost effectiveness. It is independent and well regarded internationally, with other countries seeking to emulate its success in delivery outcomes to the community. It is difficult to think of another program in which the taxpayer can have the same level of confidence in the efficiency and effectiveness of government expenditure. The deferrals decision represents an overt politicisation of the process of listing medicines in Australia and undermines the integrity of the government's own independent expert review process.

The medicines industry, along with just about every other Australian, wants the government to revert to the previous practice that allows Australians to get access to medicines in a timely manner. This is a bad decision. When it was announced in February, we said at the time that it was the wrong decision and, since then, time has shown that it was. There has been much debate recently about whether governments and political parties can and should change their minds about their policies. Political parties should be able to change their policy positions when the evidence justifies this change. This is an important ingredient for good policy making, strong leadership and a healthy democracy.

The government's decision to delay the listing of new medicines on the Pharmaceutical Benefits Scheme is one example where the Australian public thinks a change of direction is needed. There are few things more important in government expenditure than making medicines affordable for sick people and their families. The Australian medicines industry understands that times are tough, but this is one measure that the whole community has said it does not want. Given Australia is a wealthy country, with one of the best fiscal positions in the industrialised world, we should be able to afford to spend money on medicines for sick people. We could talk to you about this decision for the whole two days that you are conducting the hearings, but we understand that senators have many questions to ask. We are keen to discuss them with you, so we will leave it there and we are happy to take your questions at this point.

Senator FIERRAVANTI-WELLS: Dr Shaw, you heard my questions earlier to Mr Learmonth about the longstanding practice of requiring cabinet approval for only those new medicines with an anticipated budgetary impact of $10 million or more per annum. Are you able to assist with how long that practice has been in existence?

Dr Shaw: I would have to take that on notice, but my understanding is that it would be from about 2001. About the last 10 years, I would suspect. Certainly industry's view is for about 10 years.

Senator FIERRAVANTI-WELLS: In your submission you make reference to what is now going to be a political lottery. How do you see that panning out? How do you envisage operations under the new regime?

Dr Shaw: I think the political lottery refers to the fact that there is enormous uncertainty, certainly in the minds of companies and the broader community about how cabinet will be making these decisions. I think we have one sentence that refers to life saving and no alternatives. But we really have no other guidance about how and when it is going to occur, how long a deferral will stay in place and, if it is based on financial circumstances, when those financial circumstances are sufficiently benign that we would be able to go back to the old process. So it has made it enormously difficult for our member companies, the medicines companies, to predict how the process is going to work. Yes, there is a robust hurdle in the process of PBAC, which you have heard about already, and companies have to go through quite a rigorous process. It is bruising at times, but it is a good rigorous process. This new decision adds another hurdle to that process that has a lack of clarity and makes it very difficult for our companies to anticipate how their drugs are going to be listed in future.

Senator FIERRAVANTI-WELLS: Do you envisage a situation where potentially you are going to have to go and lobby every cabinet minister to put forward your case in relation to a new listing? We have seen criticisms in recent times about ministers outside their portfolio being lobbied in relation to a communications issue. Are companies, consumer groups or any other bodies who have a stakeholder interest in a decision going to be forced to lobby individual cabinet ministers?

Dr Shaw: Certainly it is not going to be me. I do not have enough shoes to do that! But the problem with this decision, the cabinet approach, and the direction it goes is that it creates a situation where the independence of the PBAC process takes second rung to a decision-making process in the cabinet which is inherently political. One of the major strengths of the Australian system is that, in amongst all the other stuff that goes on with listing medicines and the discussions that happen, you have the PBAC process there that makes a recommendation. This decision by the cabinet puts that to one side, effectively, and now opens up the opportunity for much more dialogue happening and much more decision making, in a process that is, as I say, unclear at best. So it opens up the opportunity.

Senator FIERRAVANTI-WELLS: So at best how much is actually going to be saved as a consequence of this deferral over forward estimates? Are we really talking nickel and dime here, penny-pinching at its worst? Can you just assist us here—all this pain for how much?

Dr Shaw: It is difficult to estimate, but our back-of-the-envelope calculation is about $20 million to $25 million a year per year for the four-year period, which in a scheme of $8 billion or $9 billion a year seems to me to be a relatively small percentage of that scheme for the impact that it is going to have on the future listing of new medicines.

Senator FIERRAVANTI-WELLS: So potentially paying for pink batts and school halls took priority over paying for medicines for people in need?

Dr Shaw: As I say, it is a very small amount of money in the scheme of things. There are obviously lots of areas that government expenditure has, but this is a relatively small area.

Senator FIERRAVANTI-WELLS: You may have followed the evidence the other day when we had a hearing in Melbourne. There were some comments made by Minister Butler, who was acting Minister for Health and Ageing. I think he dismissed comments that had been made by pharmaceutical companies as 'rhetorical flourish', if my memory serves me correctly. What is your comment in relation to that? Why would you bring in stock and begin testing with patients if you could not sell the medicines in the long run? Why would you go out and test on a patient group that has little prospect of having this medicine available for them in the long run?

Dr Shaw: One of the reasons that we went into the memorandum of understanding negotiations was predictability and certainty in the process. There is a very good reason for that. It is that it takes a long time to get a medicine to patients, whether that is through clinical development and research processes or even the listing process. Even in the listing process, once you have a medicine sitting there in a vial, to get the medicine through the regulatory process and the PBAC and PBS review process is quite extensive and takes a long time. Companies have to make commercial decisions about when they bring medicines to the market and which ones they choose, and that is influenced by a range of factors, including the cost of the listing process—we now know that companies have to pay for the PBS listing process as well as the regulatory process—how the drug is going to be used in the market and what is the likelihood of success. A company is not going to spend hundreds of thousands of dollars of its own money to put a drug through the process if it does not think it is going to get listed, when it has got other alternatives there. So this is causing a lot of uncertainty for companies in terms of their ability to bring new medicines. I will not name the companies but I have spoken with a number of managing directors in industry and they are genuinely concerned because they want to bring new medicines to the Australian public. They want to bring medicines onto the Pharmaceutical Benefits Scheme but, because of the lack of clarity, the lack of process and this new hurdle, they are genuinely asking me, 'Is it worth continuing the process? Is it worth us spending all this money and taking the commercial risk for something that may fall over?'

With the committee's indulgence, I will just read a little quote from one of our member companies that has made a submission. It is not a large international pharmaceutical company; it is a small Australian owned company in Pennant Hills, iNova. It has a small number of products; it is just two sentences. They talk about a couple of new therapies they are trying to bring on the PBS and the impact of this decision. They say:

> Furthermore, iNova is planning for PBS access to an in-house developed therapy, which treats a certain type of skin cancer and represents an advance over current treatments. However, we now question the worth of continuing to invest in this new formulation for Australia since its potential PBS listing could be placed on hold indefinitely.

We have a small Australian owned company trying to bring new medicines to the market and they are telling us, as are many other companies in our membership, that this decision is causing enormous uncertainty for them.

Senator FIERRAVANTI-WELLS: Just following on from that, Dr Shaw, in effect the uncertainty will likely hit hard first on the small Australian companies. Obviously, the internationals have a better buffer in terms of dealing with those issues. Are we likely to see serious issues in terms of smaller pharmaceuticals companies just going to the wall?

Mr Bruce: We surveyed our membership and we did it deliberately anonymously. Companies are commercial entities. They have legal obligations. They will not come out and signal to the market what their future plans are; hence, we did it anonymously. Eleven of those companies came back and said they were considering delaying seeking a listing through the TGA or the PBAC. Will those companies come out and put their name to it? No. They would be highly unlikely to do that. It is very risky for them to do it so that is why we did it anonymously. I think it was instructive that, in two of the responses we got, the companies specifically identified small products. Companies do not want to go out there and say, 'We're going to not do this niche product, this niche population,' but they will say it anonymously. I think what surprised us was the number, so it is not rhetorical flourish.

Dr Shaw: I think the other point to make is—and I know some previous speakers have commented on large companies and that they can cope with it—that we need to remember that this is affecting the whole industry. Even one of the companies that has had a product deferred, Mundipharma, is a relatively small company in Australia. It is has Targin, the pain medication. They have a handful of products, and this is one of their products that was coming through the PBS process. They had the expectation it was going to be listed. It has been deferred indefinitely. They have said in their submission they have stock in warehouses. They had staff ready to go to roll out this medicine, and the suggestion that this is not a costly process for companies is incorrect. It takes some time for a company to be ready for that listing start date, so this affects small as well as large companies.

CHAIR: If I could just ask quickly: could you take on notice with the fees that are necessary to be paid to the TGA for the registration of a medicine and the fees that are paid to the PBAC now for applications under the cost-recovery guidelines, would it be possible for you to give us an outline of what the costs would be in actual payment terms for a company to apply to have a medicine registered and then to apply to have it considered by the PBAC? I understand there are minor and major applications, but if you could give us a short table on that, I think that might help us clarify some of the cash costs that even a small company might bear.

Mr Bruce: We have put it in our submission: to lodge a submission with the TGA, it is $200,000; to lodge a major submission to the PBAC is around $120,000; and if you get a rejection by the PBAC and you resubmit, it is another $120,000.

CHAIR: There has been no discussion that a deferral by cabinet as opposed to a listing or a rejection has not triggered any concept. They might not make member companies pay if they had to resubmit, for example, if it was sent back to the PBAC. There has been no indication—

Mr Bruce: There has been no indication that they will need to resubmit, but if they do have to resubmit there will be a fee incurred.

CHAIR: We had a discussion before with Mr Learmonth from the Department of Health and Ageing, who—again, I do not mean to mischaracterise his words—put these cabinet deferrals into the context of companies having to manage risk. I put to him that around the risk of the PBAC's decisions there is a whole science around health economics and nearly two decades of interaction between sponsors, medical professionals, consumer groups and the PBAC, which has become more transparent in recent years. I put to him that that was a very different risk to manage, being based on data—there are very extensive PBAC guidelines about applications—as opposed to what could be capricious denial of consideration of them by cabinet. Do you have a view? Are those two comparable, or are there very different sorts of risk involved there for sponsors of new medicines?

Dr Shaw: I think it is very different, Senator. As you said, one of them is many, many years of development that the industry has been dialogue with—the PBAC. There are 300-plus pages of guidelines on how the PBAC makes its determinations and the evidence required. Obviously there are discussions and disagreements from time to time between companies and the PBAC; that is part of the process, and I think the companies are aware of that. As I say, there has been at least 10 years of dialogue on that. In terms of the broader policy funding of the PBS, there is a memorandum of understanding, coming after 12 months of careful, tight and tough negotiations with the government, whereas the cabinet deferral decision was something that came out of left field. We were notified at about the same time Lloyd Sansom was, the afternoon before the decision was announced. It is a new change. The $10 million threshold has been abandoned. The government has indicated its preparedness to systematically defer listing of new medicines, and there is a requirement about lifesaving or there being no alternatives available—one or two phrases that do not have a lot of detail around them. We were not consulted about it. We were not aware it was coming. So this is a whole new area of uncertainty for companies. In fact, in some ways it is more unpredictable because, rather than relying on the robust evidence-based process of the PBAC, we are relying on a fickle process that can be political and is unclear.

CHAIR: Just to clarify, before a PBAC consideration, there is dialogue between sponsors and between the PBAC and the Department of Health and Ageing about the expectations of evidence, isn't there? There are no guarantees, of course, around decisions, but there is substantial dialogue around what should be looked at and where the mindsets of different stakeholders are.

Mr Bruce: Many companies take advantage of an offer from the Department of Health and Ageing to discuss the submission prior to lodging it.

CHAIR: As you said, there was no discussion before this decision, was there?

Dr Shaw: I was notified on the afternoon of 24 February.

CHAIR: Thank you.

Senator FIERRAVANTI-WELLS: I wonder if you called Professor—

Dr Shaw: I would have to check my diary for the exact time.

Senator FIERRAVANTI-WELLS: Thank you. I have just a couple of questions. Obviously on the MOU, Dr Shaw, I would say, 'Once bitten, twice shy.' I think you and I have had this conversation.

Dr Shaw: I think in this very room.

Senator FIERRAVANTI-WELLS: I just wanted a timely reminder of it on the record, if I may. Basically, the government has pocketed $1.9 billion and you are left high and dry. You say that it may not technically be a breach of the agreement but is a breach of the intent. Have you sought legal advice in relation to that?

Dr Shaw: No, we have not, because it is not a legal document; it is an agreement. But there is quite a strong degree of frustration in the industry about this. We entered into discussions with the government in good faith. I think we showed ourselves to be a good corporate citizen in that dialogue, and I think we were part of the solution, not part of the problem. We struck a good agreement that had a good balance between finding savings for government and getting some policy predictability for industry and some administrative arrangements that are going to make it better for patients in terms of getting medicines listed. The minister herself has said that one of the goals of the MOU is policy stability. I think she said in her closing statement in the parliament that that is to provide policy stability for the pharmaceutical sector. So our view would be that the intent of the MOU was certainly quite clear from the industry's point of view: we wanted some stability in the policy environment, in the pricing environment and in the way that medicines get listed so that the companies could plan for the future and bring new medicines forward. Even the MOU has some initiatives in it precisely to get medicines to patients sooner rather than later.

Senator FIERRAVANTI-WELLS: With the benefit of hindsight, given the gross uncertainty for you, deferrals obviously were not on the table—the government kept that very much to itself—but, had deferrals been on the table, perhaps your consideration of entering into this MOU would have been different.

Dr Shaw: I think if it had been on the table we would certainly have liked to have had a discussion about it. Basically we finalised be MOU towards the end of 2010, in November. We went away for Christmas and then eight weeks after Christmas there was the new announcement about deferrals. The intent of the MOU is to provide savings for government, predictability for industry and improved access for patients. Our view would be that the deferrals decision is in breach of the intent of the MOU.

Senator POLLEY: Thank you for your evidence. When you said the new cabinet process in making this decision is fickle, does that mean the previous government's arrangements in cabinet were fickle as well, the $10 million, and there is now politicisation of the process with this government which was not there in cabinet before? Can you explain to me how and when the fickleness came to bear?

Dr Shaw: Certainly one aspect is the $10 million threshold. Previously medicines below $10 million did not have to go to cabinet. In fact we were arguing that the threshold should be increased, given that it had not been increased for 10 years. I guess the difference here is that cabinet has indicated that it is systematically prepared to defer the listing of some medicines for what appear to be broader financial reasons.

Senator POLLEY: Can you explain 'systematically'?

Dr Shaw: I think it was raised earlier. There are one or two examples in the previous 10 years where the government decided to do that and then in the last five months we have had six deferred, ostensibly for budgetary reasons—the fiscal situation. I would regard that as a new change combined with getting rid of the $10 million threshold and the articulation of some new criteria around decision-making, life-saving and no alternatives. I am not aware that they have been used before.

Mr Bruce: Also coming straight back to the MOU. We have sat down with the government for a number of months and we thought we came to an agreement about future management of the PBS. At no point was it put on the table that the listing process would be changed. In fact, in terms of the intent of the agreement, the discussions, most of those things were discussed.

Dr Shaw: That is where some of the frustrations with the industry comes in because we literally had spent six to 12 months negotiating an agreement with the government on the framework for the Pharmaceutical Benefits Scheme for the next three or four years and literally the legislation was passed three or four months before this announcement.

Mr Bruce: With our assistance.

Dr Shaw: For the industry it raises the question: if we are negotiating a framework for the Pharmaceutical Benefits Scheme on how medicines are going to be dealt with on the PBS for the next four years, once the agreement is done, isn't that it? The fact that it came so soon after the MOU—we think the MOU was a good agreement. It is a good framework for the PBS. The deferrals decision within the months of that agreement being finalised was very disappointing to say the least. It has led to a lot of uncertainty and frustration in the industry.

Mr Bruce: A bad taste in the mouth.

Senator POLLEY: From evidence given this morning it is my understanding that there has not been any breach of the memorandum of understanding. To go to your evidence in relation to commercial risk, considering your members are, in my understanding, moneymaking businesses, which enter and do research to develop new medicines to bring onto the market and to make money, why should they be treated any differently in terms of their commercial risk from any other product which comes onto the Australian market?

Mr Bruce: That is exactly what we are saying. This industry is not asking for any handouts. The government has decided for good reasons that it would be the effective monopsonist, the only purchaser of medicines in this country. That means that the certainty and confidence around the industry is highly dependent upon and sensitive to changes in government practice. That is why there is no difference.

Dr Shaw: There is no doubt that the medicines companies are there to be commercially successful. I would be concerned if they were not, frankly, because it is that commercial success that then leads to those medicines and vaccines eventually getting to the public. That is why they do it. As I say, we literally had just finished negotiating a four-year agreement on a pharmaceutical benefit scheme. We had long discussions—and Senator Fierravanti-Wells has alluded to them—last year in this room about the framework for that MOU, what it was designed to do and the long-term future of the PBS. As an industry engaged with the government, we felt that we had a good agreement. We showed that you could do business with this government. It is a good agreement. As I say, the disappointment came within several months after that. We have a decision that has had a major impact on our members and a major impact on the listing of new medicines on the Pharmaceutical Benefits Scheme. Practically every other community group in the country has recognised this. It is not just an industry issue. Patient groups, doctor groups, the generics industry and everyone else recognises this. It is very frustrating to have just finished negotiating a major agreement and then have this happen.

Senator POLLEY: In relation to the assertions in your submission, you talk about the fact that you have surveyed your member companies on future trials and investment in Australia. We can certainly go in camera, because I do take into consideration the commercial-in-confidence nature of this. Through you, Chair, I am more than happy to move that we go in camera so the witnesses can name their member companies.

Mr Bruce: Sorry, Senator, two things: first of all, we did not survey them about R&D; we surveyed them about the delay in submitting submissions to the TGA and the PBAC; and, secondly, there is no point in going in camera on this one because we, as I said, surveyed them anonymously. These companies are not even going to come to us in many cases and give us that information, because that would, in effect, risk signalling to the market.

Senator POLLEY: You talked about 11 companies previously in your evidence—

Mr Bruce: Eleven companies who are considering delaying lodging a submission to the TGA or the PBAC.

Senator POLLEY: Can you name those 11 companies?

Mr Bruce: We surveyed them anonymously.

Dr Shaw: To be honest, I would have to get some advice before I would be prepared to do that. As I say, we do not know but, even if we did, I would have to get some advice from the companies about whether they would be happy for me to do it.

Mr Bruce: We would have to re-survey them and ask them to put their names to it.

Senator POLLEY: If you are not going to name them we can move on. We have limited time to ask questions. You assert in your submission on page 74 at clause (c) 'By moving away from a rigorous, evidence-based and apolitical PBAC process for determining PBS listing' and it goes on. However, the evidence that was provided by the PBAC chair this morning—I believe you were in the room at the time—said that there has not been any undermining of their independence or the process by which they go through recommendations and that it always has been the prerogative of the government of the day to make a decision about what goes on the PBS.

Dr Shaw: The first thing to put on the record is that at no stage have we questioned the integrity of the PBAC process. In fact, I think, if anything, we, along with all the other groups in the community, have, if you like, defended the integrity of the PBAC process. We obviously have our arguments with it. There are times when there are arguments about evidence and what they consider and what they do not consider. There was some discussion about that earlier in the day. Just to put it on the record to make it absolutely crystal clear: there is no criticism from the industry about the integrity of the PBAC process.

In terms of the cabinet's prerogative, as I said in my opening statement, we recognise that ultimately the government has to make decisions on it, but we have said that it needs to be done with care and sparingly. I think the experience of the last five months has shown what happens when that is not done. We have had medicines deferred—and the example has been raised already—when cabinet has made decisions which have left patients missing out. I mentioned a two-tiered health system and the lack of access and the lack of clinical trials and research. We have a case study of a health system that has been screwed down in terms of costs savings so much so that industry has given up on it, and it is just across the Tasman. It is in New Zealand. If you go to New Zealand, you will find that the industry has basically given up on New Zealand. The number of clinical trials done in New Zealand is very small. The industry has abandoned New Zealand. There is no R&D. The industry has given up. We are starting to see worse health outcomes in cardiovascular disease from the delay in listing

medicines there. Patients in New Zealand have to wait many more years than in Australia. There are adverse events in hospitals when the government switches suppliers. New Zealand is characterised by having much older medicines than Australia. We have patients sometimes approaching the companies here in Australia trying to get access to medicines because they are not available in New Zealand.

As I say, the industry have given up. This is a case study of what can happen when a government puts expenditure and costs ahead of the broader health outcomes and the benefits that the health system brings. I do not want to see that happen here. One of our strengths here in Australia is having a PBS that is well funded and run well. Yes, it is well managed financially but it also delivers choices and benefits—economic and social—for the broader community. I am proud to say that the industry have been a big part in that. We have runs on the board in helping to manage that.

Senator POLLEY: Based on the evidence that has been given to this committee, isn't it fair say that unfortunately there are always going to be patients and members of the community who will not have access to certain medications on the PBS? Is that not the case?

Dr Shaw: Absolutely, and that is part of the PBAC process. As we heard earlier today, they look at the clinical and cost effectiveness in terms of health outcomes and the particular benefits of that. That is different from when the government decides on a financial basis or for other reasons not to list medicines, and that is one of my concerns. We have an independent process that looks at the clinical and economic needs and benefits of a medicine, and it makes recommendations. The change has been in the last five months that the government now says, 'That is all fine, but we cannot afford it because of the budgetary situation.' It has nothing to do with the clinical benefits. We heard some examples today that there are patients who potentially can potentially miss out as a result of the decision. I have to check the transcript, but I am pretty sure that the minister herself said in one of the doorstops that there were patients around who may have to wait and have their access to better medicines delayed. This has been done for financial reasons and not for health economic reasons.

Senator POLLEY: Given the almost record number of major submissions considered by the July meeting of the Pharmaceutical Benefits Advisory Committee—I think there were some 31 major submissions—it appears that the decision has not had any really chilling effect on new drugs being brought forward, has it?

Dr Shaw: As I say, I contend that. Obviously the numbers are there, but if the feedback from the industry is anything to go by, a lot of the companies that are bringing new medicines forward are very worried about this. They cannot plan. There is also a time delay with this. Companies have multiple products in their pipelines and they have to consider how to bring them to market and how to bring them onto the PBS. This is causing enormous uncertainty for the companies.

Mr Bruce: All those submissions that were heard in July were lodged in March, which means they were prepared well before the announcement of this decision.

Senator POLLEY: So are you contending that there will be far fewer submissions put forward in the future?

Mr Bruce: We are saying that the uncertainty, as we have indicated, may potentially reduce the number of submissions that are lodged.

Dr Shaw: If you are a company that is trying to guess whether you have a lifesaving medicine with no alternative on the PBS, you have to make a judgment call on that at the moment.

Senator POLLEY: But not every medication listed on the PBS is for life-threatening illnesses.

Dr Shaw: Exactly, and that is the point.

Senator POLLEY: I will move onto your assertion within your submission that the PBS growth is at or below the CPI. I was just wondering if you could explain to the committee where you get your figures from, as opposed to the evidence that was given by the department that the increase was somewhere in the range of six to seven per cent annually?

Dr Shaw: The submission has a wide range of data to make the argument, which I think it makes persuasively, that the PBS is not growing out of control. In fact, it is growing at reasonably low rates; it is certainly growing at below historic levels. The latest data that I am looking at here from Medicare Australia says that it is a five per cent annual growth rate, and it could be ranging up to about six per cent. That is nominal, which is the other thing to bear in mind. We had the Department of Finance and Deregulation here earlier in the day talking about the government's real growth rate of expenditure being at two per cent. If I was to adjust these figures using the inflation rate of roughly three and a bit per cent, that would bring the PBS growth rate, in real terms, to somewhere in the order of three to 3½ per cent. My argument would be that even on those figures the PBS is not growing out of control. Similarly, we know that the PBS, as a proportion of GDP, is 0.64 per cent,

which is about the same level it has been at for the last decade—that is, the economy is growing with the PBS, so the PBS is not taking up more of the national income. The Treasury's own projections, as I alluded to, in last year's *Intergenerational report*—these are not my numbers; these are Treasury's numbers—suggest the PBS is going to be 0.7 per cent of GDP by 2020. That is almost the same level, only rising slightly to 2020. The long-term average growth rate of the PBS is 12.2 per cent. Six per cent in nominal terms is low by historical comparisons. Compared with OECD countries, Australia's level of spending is, as I said, about 0.6 per cent or 0.7 per cent of GDP and that is well below a range of other OECD countries, like Japan, Germany, France, Belgium, Austria and Korea. The OECD average for 18 countries is 0.8 per cent of GDP.

I understand the argument about PBS growth rates, and there are obviously different figures you can use—and I think we have put all this in our submission to argue the case—but the PBS is not growing out of control. It is not an unsustainable program. The country can afford it.

Mr Bruce: One of the things—

Senator POLLEY: I have limited time, so could I move on, with all due respect. If you would like to put something on notice to add to Dr Shaw's comments, I am sure the committee would be more than happy to receive that. In relation to your assertions about whether or not the country can afford to continue investing in excess of $9 billion, as one component of the health budget, that is something that governments are elected to administer—the country's budget—but, even from the evidence that was provided previously by the chair of the PBAC, I do not think it is realistic to expect that, for every recommendation for every medicine that comes through, any government is going to be able to afford to continue to put those on the PBS. Your assertion in your submission is different—that for anything that the PBAC recommends, a government should support it. So a government should defer the responsibility of inclusion of PBS medications to that committee?

Dr Shaw: One of the challenges is that, of all the areas of health expenditure under the federal government, the Pharmaceutical Benefits Scheme is one of the most rigorously evaluated. The PBAC does a fantastic job, sometimes to the chagrin of my members, of managing the Pharmaceutical Benefits Scheme or recommending medicines for the PBS. Every medicine that is recommended to cabinet has been evaluated for clinical and cost-effectiveness. The PBAC looks at all of this and says, 'Yes, this medicine is cost-effective, based on a health outcome approach.' You cannot say that about every other area of health expenditure.

Senator POLLEY: But you cannot expect the government to give a tick automatically.

Senator DI NATALE: Thank you for your submission. You say in your submission that you are concerned that the government is moving towards a two-tiered system, where some people can afford better treatments for things like schizophrenia, but that has always been the case, hasn't it? There have always been drugs available, not through the PBS, with minor therapeutic benefits, but they are not cost-effective to government. We have always had that, haven't we?

Dr Shaw: That is right. My concern is that this is becoming more problematic and more systematic, if you like. We have a government that is now suggesting that, yes, these medicines are actually cost-effective from a taxpayer basis. We have seen this. The PBAC has recommended that it is value for money for the taxpayer to subsidise these medicines, but the government is saying, 'No, we can't afford them.' 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.

Senator DI NATALE: Given the concern you have about moving towards a two-tiered system, what do you think about the government subsidising the private health insurance industry, which obviously gives us a two-tiered system?

Dr Shaw: Unfortunately, the referrals issue has been such a distraction for me for the last five months that I have not had time to focus on the private health insurance rebate debate.

Senator DI NATALE: Your case would be a hell of a lot stronger if you could point to a few examples of where industry has either delayed a product for listing or at least pulled some money out of research in a particular area. If you could point to one of those specific examples, your argument would be a much stronger one to advance. But you are obviously not prepared to do that or cannot do that for the reasons that you have already outlined. Given the concern that you obviously have, have you issued a profit warning yet?

Dr Shaw: Unfortunately, Medicines Australia is not a profit making organisation.

Senator DI NATALE: Have any of your member companies?

Dr Shaw: One of the examples that I can point to is across the Tasman. When you look at what has happened in New Zealand over the last 20 years, the industry has basically abandoned New Zealand. There are medicines available there. Some of the medicines available in New Zealand are forty years old and have become lesser used in Australia. Basically, a lot of the New Zealand market is now run out of Australia because of the commercial environment in New Zealand. Patients in New Zealand have to wait much longer for medicines than patients in Australia. There is various data that we are happy to provide you with that shows that New Zealand, in terms of access to medicines, is one of the worst countries in the OECD.

Senator DI NATALE: But you are not comparing the regulatory regime in New Zealand with the deferral of six medications here in Australia, are you?

Dr Shaw: There are similarities. The similarity is that you have a government for budgetary reasons saying that we cannot list these medicines. I am not saying that Australia has reached the New Zealand model yet—I would happily debate that. But my concern is that government is starting to say things like 'Yes, these medicines are cost effective and we can see that a modern industrialised country should be able to access these but we cannot afford them.' My concern is that if we continue down that path will we head towards that model. We will end up with a cap model such that patients will have to come to Australia for medicines or such that patients will have to wait six to 12 months or such that some medicines will not be available. Patient choice and having a variety of options for doctors to use are important parts of a modern, wealthy, industrialised country. Having a suite of options that doctors can use with their patients is a good thing. Doctors can say, 'This chronic pain medications or this schizophrenia drug might not work for you, but this one we can try because it is available.' That is an important part of a wealthy country.

Mr Bruce: And basically they have been evaluated as being cost effective. They are value for money and will return more to the community than they cost.

Senator DI NATALE: I share your concerns about the decision. I just think that trying to draw an analogy between the PBAC and the New Zealand system for regulating medications is a very long bow and I do not think that it helps you advance your argument. I want to use a quote that you have used in relation to the sustainability of the PBS. You are correct in that there are many different ways of looking at this question of sustainability. But to quote figures for the year to March and highlighting those as coming in at under CPI is a little disingenuous when you understand that there is significant volatility and that people stockpile their scripts until the end of the year. Do you have any concerns about the fact that you have used that as evidence to show the sustainability of the PBS?

Mr Bruce: You will find that we in fact acknowledged in our submission that that was volatile. We agreed, in fact, that for the coming year it will probably come in at around 6.5 per cent. What we have questioned is why that is an inappropriate growth level? What is the context around that growth? Why, given where we stand against our international partners, given that it is flat against GDP, has it not been contextualised? That figure is never put into context.

Senator DI NATALE: The question that I have is if you have an increase of three per cent you are looking at by 2020, say, an amount of about $16 billion. If you put it up to six or seven per cent, obviously that is an exponential increase and you are looking at a cost of about $34 billion. There is a significant difference because of the nature of the exponential growth of the PBS. Do you not accept that?

Dr Shaw: The numbers have been bouncing around. The same numbers that were used 12 to 18 months ago to argue that the PBS was growing out of control at rates of 13 per cent or 14 per cent show that 12 months later the PBS was growing at three per cent. It is the same dataset. We do not dispute that there is volatility. That is one of the reasons we tried to smooth that out by using annual figures only. We do not even talk about monthly or quarterly growth rates, as they are meaningless. We use annual growth rates. The fact is that the annual growth rate of the PBS in around March 2011 was three per cent. About 12 months earlier in March it was seven per cent. And in March a year earlier it was around 10 per cent. The point is that those numbers were being used to argue that the PBS was growing out of control. In the charts in our submission you can see the cyclical nature of that. The point is that it bounces around. The reason we used those numbers is that at the time when people were saying it was growing out of control it was growing at three per cent or whatever the figure was—close to the inflation rate.

Senator DI NATALE: I take your point; I think it is a good point. But if you accept that we are looking at a growth on average of about six or seven per cent, which I think is a reasonable guesstimate, do you think that is sustainable?

Mr Bruce: One of the things is that when the government came and expressed anxieties around the fiscal elements of the PPS we sat down with them. We tried to put in long-term policy settings which would get ongoing efficiencies to the market. They have not even flowed through yet, yet we are back here talking about growth. Last year we said, 'Okay, let's sit down and find out how we're going to get that growth down. The pressure in terms of growth is the least downwards. Let's see how that plays out.'

Senator DI NATALE: You are referring to the $1.9 billion expected to be saved through the MOU. If those savings are not materialised, do you think that the government would have grounds for further reform? At this stage those savings may not be materialised.

Dr Shaw: There are a couple of things in the MOU. One is that it effectively has a guarantee mechanism in it; it guarantees the price cuts that are in it. That is one of the things that we negotiated. The guarantees weighted average price reduction of around 23 per cent, I think, across the PBS or parts of the PBS to deliver the government those savings. The other thing the MOU has is—

CHAIR: Dr Shaw, I need to ask you to wind this is up very shortly, as we do have to break.

Dr Shaw: The other thing the MOU has is an agreement to work with government on mutual numbers around the PBS, exactly for this reason, because every time we come to a Senate committee hearing or every time we start to debate the PBS we seem to dance around the maypole about what the PBS growth rate is. One of the good things in the MOU is that we have agreed that we are going to sit down with the government and work out what was actually forecast in the past, let alone what is happening in the future—actually work out what happened.

Mr Bruce: And what is driving it.

Senator FIERRAVANTI-WELLS: Did you have any inclination at all about the deferral?

Dr Shaw: No.

Senator FIERRAVANTI-WELLS: Despite your closeness to the MOU—

Dr Shaw: No, Senator. I have to say that that is one of the disappointing things. We spend a lot of time working with the government and being part of the solution not part of the problem and developing an agreement.

Senator FIERRAVANTI-WELLS: So since then have you worked—

Dr Shaw: The afternoon before it was announced.

CHAIR: Dr Shaw, a couple of colleagues would like to put further questions on notice to you. They are going to submit them in writing. The secretariat will get them to you shortly. I appreciate the limitations, but it would be good if you could get them back to us within a week or so, which would allow us to consider them in the consolidation of the report. Thank you both for your time.

Proceedings suspended from 12:17 to 13:15

BENNETT, Ms Carol, Chief Executive Office, Consumers Health Forum of Australia

WISE, Ms Anna, Senior Policy Manager, Consumers Health Forum of Australia

CHAIR: Welcome. Information on parliamentary privilege and protection of witnesses and evidence has been provided to you. The committee has your submission. I invite you to make a short opening statement, at the conclusion of which I will invite members of the committee to put questions to you.

Ms Bennett: We really appreciate the opportunity to be here today to expand on our submission. For health consumers, affordable and timely access to the best available medicines is absolutely essential. Access to medicines through the Pharmaceutical Benefits Scheme is a necessity in the treatment of many conditions and these medicines can save, prolong and enhance life for millions of Australians. For many years consumers have supported the process for the listing of medicines on the PBS in Australia, with assessment and listing by the expert independent Pharmaceutical Benefits Advisory Committee, PBAC.

As health consumers, they knew that all medicines listed on the PBS went through a fair and transparent process, with the criteria for listing outlined in legislation and with opportunities for health consumers to contribute to the process. As taxpayers, they knew that only medicines that were deemed to be cost effective by a panel of experts would be publicly funded through the PBS.

Now, however, the government has added an additional step to a process that worked well and that was well respected. Even after medicines have received a positive recommendation for listing from the PBAC, after going through one of the most rigorous assessment processes in the world, they must now go through a process of approval by cabinet, regardless of their financial impact. We believe this is a substantial change from the previous arrangement where only drugs with a financial impact of over $10 million per year, in any of the first four years of PBS listing, had to be considered by cabinet.

This is a major change. It happened without any consultation with any of the affected stakeholders, including health consumers, and the only rationale provided for this change was the need to bring the budget back into surplus. Seven medicines and a vaccine were deferred in February 2011 as a result of this cabinet review. Health consumers are asking: how many more will follow?

We completely reject the arguments that the decision to indefinitely defer medicines listing by cabinet does not represent a change in policy. While we accept that the government has the final say on recommendations of the PBAC and we know that that has been the case all the way along, we note that the rejection of listings has only occurred in two previous instances.

Policy is meant to be a course of action, not a set of words. For consumers, policy is taken to mean what is done and the reality is that positive recommendations from the PBAC have almost invariably been approved for listing on the PBS. Whatever spin you put on it, this represents a major policy shift. CHF has seen an enormous level of consumer concern about these changes, unprecedented in our 24 years of advocating for Australian health consumers. In June, 60 health consumer organisations joined with us to condemn the policy change and call for its reversal. More have contacted us since then, supporting our campaign. More than half of the submissions to this inquiry have come from individual health consumers or consumer organisations. This level of concern cannot be disregarded.

Our submission outlines four broad areas of consumer concern. Firstly, consumers are tremendously concerned that they will face further delays in access to essential medicines. The listing of some medicines has already been deferred indefinitely. How long will consumers have to wait to access these? How many more medicines will be deferred as a result of this new process and for how long? And how will cabinet manage to fit consideration of every single new medicine into their already packed agenda?

Secondly, consumers are concerned that there is no transparency in the new process. We do not know what criteria are being used to decide which new medicines are listed, whether cabinet is drawing on any additional evidence apart from that considered by the PBAC, or what expertise is available to assist cabinet to make its decisions. The Department of Health and Ageing states in its submission that there are no additional formal criteria to inform the deferral of medicines and that the department does not provide advice to cabinet about the deferrals. What expertise do the 20 members of federal cabinet have that is not currently represented on the PBAC? And how can we be confident that their decisions are based on anything other than budgetary considerations?

Thirdly, the lack of any transparency has created real consumer concern that a new political element has now been added to the process. In the absence of any credible explanation of why some medicines have been deferred while others have been listed, there is really no other conclusion that consumers can reach. Consumers are concerned that the listing process will become open to political whims and external interference. Consumers do not want a situation in which drugs are listed on the PBS to win votes or boost opinion polls; nor do they want a process which allows those consumer organisations with the loudest voices or the most media and political nous to see their drugs listed while other groups must wait indefinitely. And they absolutely do not want to see a process in which pharmaceutical companies can directly lobby cabinet members to achieve a positive outcome.

Fourthly, and finally, consumers have rejected the argument that deferring listing of medicines on the PBS will bring the budget back into surplus. Quite aside from the fact that the PBAC already considers whether these medicines are cost-effective, there are considerable savings to be made across the budget if people have access to the right medicines that meet their treatment needs. Consumers receiving the right treatment will require fewer hospitalisations, fewer appointments with health professionals and fewer treatments to address side-effects. And, beyond the health budget, consumers receiving effective treatments are more likely to be able to participate more fully in society, contributing to the workforce and as taxpayers.

In conclusion, we ask the senators to hear the concerns of health consumers right across Australia. At the very least, we ask that the committee calls for a higher level of transparency around what criteria, evidence and expertise the cabinet is using to make their decisions about medicines listings, and to reintroduce some certainty and reduce the politicisation of this process. Ultimately, however, we ask the committee to seek the reversal of this short-sighted decision by government so that Australians can return to the system that supported consumer access to the best available medicines for decades.

CHAIR: Thank you, Ms Bennett.

Senator POLLEY: Thank you for your submission. I just want to take up the point you made in relation to not understanding the criteria on which the government now base their decisions on what will be listed and what will not, after it has been recommended to them by the PBAC. Could you outline to me what the cabinet process was for making the same decisions when there was a $10 million buffer there? Can you tell me what the criteria were that were used by cabinet previously?

Ms Bennett: While the cabinet may not have made its criteria specific and public and transparent, consumers understood that there was a threshold and that that threshold was generally $10 million every year over the first four years of listing of those more expensive medicines, and I suppose that gave consumers some level of assurance that there was actually a transparent, independent, rigorous process that was gone through, that enabled the government to make a decision that was based on factors, with cost as a significant cost factor as opposed to other factors that the cabinet may now be considering, given that there is no imperative and no threshold.

Senator POLLEY: We have had evidence given to us by the chair of the PBAC in relation to this, and he outlined the process: very rigorous and independent—the way it should be, in my view. I am sure everyone here shares that view. But what you say in your submission is that, once that recommendation is made, it always has been the prerogative of the government to take those recommendations and then make the final decision. You suggest in your submission that the cabinet should not have the final, arbitrary, say in what is listed. If it is not to be the government, who should it be?

Ms Bennett: We are not suggesting that at all. In fact we fully accept that the government has the right and should make the final decision about which drugs are listed. The issue is that there has been a process that has worked really well in this country for over 60 years. People respect it. It is respected internationally as one of the best practices in the world. Consumers understand it. Companies who are listing their medicines understand it. Health professionals understand it. We now have a policy change—and I would argue very strongly that it is a policy shift—because we no longer have the government looking at some kind of threshold amount, which would then make the case that there is a substantial reason for the federal cabinet to be involved in those decisions where budgetary concerns are the highest priority. In fact they have only ever rejected the recommendations of the PBAC in two instances, as we heard this morning. To me that is a policy shift.

We are now looking at a situation where you have got the federal cabinet involved in the micromanagement of decisions about every single drug that goes up in the context of all the other considerations that federal cabinet must have and that creates a problem of access. It creates a problem of transparency because we do not know on what basis every single one of those drugs is being considered by the cabinet. It will ultimately create a backlog of drugs that are going up to cabinet and being deferred. The PBAC is meeting three times a year. If the cabinet is considering every one of those drugs, that becomes a real issue in terms of resources and how much the cabinet can actually do to consider every one of those drugs that goes up. Consumer access is the concern because quite

clearly it may well become compromised if the number of applications that are going through to the cabinet become backlogged because there are simply not the resources to consider them all.

Senator POLLEY: You are not advocating then that just because a drug is recommended by the PBAC it should automatically be given approval by the government, bearing in mind that if we spent every dollar that the government has for health just on the PBS it still would not be enough. There has to be a process and governments make the policy.

Ms Bennett: There is a process and it is a process that has worked really well for over 60 years. That process is considered one of the most rigorous processes by world standards. It is not an automatic approval process for those companies that look at listing their drugs on the Australian market. As you heard from Professor Sansom this morning, it is an incredibly rigorous process that takes into account the costs and the savings that those drugs will produce and the benefits that those drugs will produce for the Australian community. So there is already a process that works to consider those issues.

The question is what benefit and what added value does it entail to have the federal cabinet members poring over what has already been a rigorous process to get those applications through to the cabinet? What criteria are being used to make that assessment? We are concerned about the sustainability of the health system well into the future too but there are very few programs in the health sector that are actually evaluated to the degree that medicines are in terms of cost effectiveness, yet we still make decisions about which of those should be funded which should not. This is one of those programs that has already demonstrated cost effectiveness before those recommendations are made.

Senator POLLEY: You talked again about the previous process of cabinet. There was no written criteria for any decision made by cabinet in relation to anything above $10 million. That was the evidence we were given. So nothing has actually changed with the process. The only reason we are here now is that some drugs were deferred. I want to move on to your support for the $620 million telehealth initiative, which I understand you are supportive of. What I want to ask is: why do you think new drug subsidies costing hundreds of millions of dollars should not be subjected to the same level of government scrutiny as any other decision-making element of the health program? What sets medicine aside from every other element of the health budget when we are still talking about taxpayers' money?

Ms Bennett: Absolutely. Firstly, I would argue that they are already subjected to very high and rigorous standards of cost-effectiveness through the PBAC process, one of those programs that is unique in terms of assessing the cost-effectiveness before the drugs are actually funded, whereas other programs are not: they have to produce some kind of benefit that is evaluated for cost-effectiveness once they are implemented. We believe the telehealth initiative is a very good initiative. There are many initiatives that the government has funded and is funding, particularly around some of the new health reform proposals, that we have been incredibly supportive of because they offer the opportunity to provide high-quality, cost-effective, good access to health care for Australian consumers—in that instance, particularly rural and remote Australian consumers, who really do need more equitable access to health services.

The only criterion that we have been presented with around the need to evaluate every single drug that the PBAC recommends is the short-term budget considerations. To our mind, the provision of cost-effective medicines to the Australian community is the absolute cornerstone of providing quality healthcare treatment. We are a country that can and should be able to afford to provide access to essential medicines, and in fact that access will save us money as a community well into the future. So I cannot see why short-term budgetary considerations should be the primary objective in the cabinet's decision to defer the listing of these medicines.

Senator POLLEY: In fairly recent times there was a media release from the CHF which referred to the shelving of a drug to help people with bowel cancer. Can you tell me which drug that was?

Ms Bennett: Erbitux. Yes, that was one of the seven medicines that were originally deferred back on the 25th.

Senator POLLEY: I think it has been listed, hasn't it?

Ms Wise: The situation with Erbitux was that it was deferred while the assessment process went through for a pathology test associated with it to be listed on the MBS. My understanding is now that it has been listed. I believe the pharmaceutical company is paying for the pathology test while the MBS process goes through.

Senator POLLEY: Could you just elaborate on how your perception is that now all of a sudden the process has been politicised and there is going to be lobbying by drug companies and other organisations, and how that differs from decisions that have been made by previous governments in relation to cabinet decisions and drugs. As a senator I get lobbied all the time by interest groups, but at the end of the day the process is very clear: the

PBAC will make a recommendation and no drug can be listed on the PBS without that recommendation. So how is this process being politicised?

Ms Bennett: I think that when the cabinet is considering more drugs, as it is now—and we are not just looking a threshold of $10-million-a-year-over-four-year drugs, which are the high-cost drugs; we are looking at however many multiples of drugs which are now being considered by cabinet—it is being exposed to the potential for the cabinet members to be lobbied very directly both by consumer groups and by pharmaceutical industry companies who have very strong vested interests in the listing of those medicines. So it increases the opportunities for that politicisation to occur. For consumers, that is a real concern—particularly when there is no clear criteria on which cabinet is making decisions—if it means that 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.

Senator POLLEY: Page 5 of your submission, in the conclusion, states:

While it may be necessary to minimise PBS costs, CHF argues that allowing Cabinet to be the final arbiter of which medicines should be available to Australians is not the solution.

If it is not the cabinet that makes the final decision about taxpayers' money, I ask you again: who should be doing that?

Ms Bennett: As I have said, we do believe that the government has a responsibility to make the final decision and always has. However, that has now shifted to all medicines as opposed to just high-cost medicines, whereas previously there was an expectation that the process itself provided the assurance that government needed before it listed those drugs. I suppose for us the issue is that there are other ways of achieving cost savings, if cost savings—and they seem to be—are the major consideration that the government is taking into account when it comes to this policy.

CHAIR: A number of committee members, witnesses and submissions have talked about whether or not we should be subjecting pharmaceutical spending to the same hurdle that we subject other spending to. That has usually been discussed in the context of whether or not cabinet should be making these decisions. Isn't it fairer, however, to characterise that the hurdles for pharmaceutical spending before it gets to that point are actually much greater than any other similar part of the health system?

Ms Bennett: Absolutely. This is one of the few areas of health funding expenditure that is put through the kinds of rigours that these applications have to go through and actually demonstrate cost effectiveness before they are funded.

CHAIR: Before the minister is even allowed to take it to cabinet to recommend its subsidy—is that the case?

Ms Bennett: Absolutely, so it has been put through the hoops already. Very few health treatments or initiatives actually can show that they demonstrate that kind of cost effectiveness before they are funded.

CHAIR: And one could argue that our health system would in fact be better off if, at the pre-cabinet stage, before decisions about resource allocation were made, other health interventions were actually considered through a similarly rigorous process.

Ms Bennett: Yes, although I guess practically that might be difficult to achieve. Medicines are a unique part of the health system that can actually be evaluated for cost effectiveness, whereas many others cannot necessarily demonstrate that so clearly. We would support that if you could do it in a way that was efficient, but unfortunately that is not the case—but this is one of the few exceptions.

Senator POLLEY: Isn't it fair to say that in the past some medications have taken years to be approved by cabinet?

Ms Bennett: That may well be the case, although I am not aware of any specific medicines that that applies to. Generally speaking, the process tends to be more lengthy when it applies to the higher cost drugs because of that cabinet consideration. In fact, we spoke to an earlier Senate inquiry—this year or late last year—about the need to lift the cabinet threshold from $10 million to ensure that consumers had faster access to medicines. The problem was that the cabinet's consideration of even those drugs that were $10 million or more a year was holding up the process and preventing consumers from getting faster access to those medicines.

Senator FIERRAVANTI-WELLS: I was present at that hearing. I think, Senator Polley, you will find that the issue about the timing is very pertinent because under this government it has blown out to up to nine months as opposed to the time that it took during the previous government. That was the reason why there has been a real issue in relation to timing. Ms Bennett, that is really the point you are making at page 3 of your submission about

the delays and the substantial agenda. We are finding that the time has blown out. We have discussed this in Community Affairs estimates. In relation to the survey, I gather that you have only taken a snapshot of the survey comments.

Ms Bennett: Yes.

Senator FIERRAVANTI-WELLS: In relation to the impact on consumers, one of the comments is that, 'Consumers will have to suffer for the sake of political gain.' I think that was the general flavour. Also, interestingly enough, in the 'Do you have any other comments?' component of your survey there are some pretty strident comments by those who were surveyed, particularly about transparency and the lack of expertise of cabinet to make these decisions.

Ms Bennett: Yes.

Senator FIERRAVANTI-WELLS: The longstanding practice has been that fewer than 10 million are signed off by the minister. It is basically a routine signing-off based on the PBAC recommendations. That is what made it more expedient, and generally the turnaround with the minister was under different regimes—basically a manageable period of time.

Ms Bennett: Yes.

Senator FIERRAVANTI-WELLS: I believe that you have a representative on the PBAC. Is that the case?

Ms Bennett: We do.

Senator FIERRAVANTI-WELLS: And that is still Mr Messer?

Ms Bennett: Yes.

Senator FIERRAVANTI-WELLS: Professor Sansom gave some evidence earlier, which I do not know if you heard, about the closed-door session of the PBAC in March after this decision. Are you aware of that?

Ms Bennett: Yes.

Senator FIERRAVANTI-WELLS: And Mr Messer was at that meeting?

Ms Bennett: Yes, he was.

Senator FIERRAVANTI-WELLS: Did he report back to you or back to your organisation about that meeting?

Ms Bennett: No, he did not. My understanding is that the members of the PBAC are bound by confidentiality agreements. We do not tend to have discussions with Mr Messer about the deliberations of the PBAC, because he is bound by those confidentiality requirements.

Senator FIERRAVANTI-WELLS: So Mr Messer's appointment was to him personally rather than to the Consumers Health Forum, but he just happens to be—

Ms Bennett: He was a nomination of the Consumers Health Forum. He is there to provide consumer expertise. We have had discussions before in other committee inquiries about the limitations that there are on single consumer representatives to be able to be in a position to represent the broad range of views of consumers. And certainly this is a good example of where that system falls down, when consumer representatives are bound by confidentiality and are unable to consult with and represent the interests of a broad range of Australian health consumers.

Senator FIERRAVANTI-WELLS: As you said, there has been unprecedented response following this decision as far as your membership is concerned. It is quite unprecedented in terms of the 60 organisations that have banded together, so suffice to say that you are speaking with a very large voice when you put forward these views.

Ms Bennett: I am not aware of any single member organisation of ours who has not supported our position on this. It has been the one issue that has had united support from all of our members.

Senator FIERRAVANTI-WELLS: Previously Dr Shaw was questioned about his assertions about the development of a two-tier system for those who can afford it and for those who cannot afford it. It is very clear that the survey results more than vindicate Dr Shaw's assertions in relation to the development of a two-tier system. If you have got the money you can afford the medicines, but you if you do not have the money you will have to go without.

Ms Bennett: Absolutely. Out-of-pocket costs for Australian health consumers are enormous already by OECD standards. We are paying huge out-of-pocket costs, as well as our contribution as taxpayers. 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.

Senator FIERRAVANTI-WELLS: When did you first become aware of this decision?

Ms Bennett: When the minister issued a media release. I think it was on 25 February this year.

Senator FIERRAVANTI-WELLS: Suffice to say that you are a very active group so you keep your ear very much to the ground. Did you have any inkling at all that this was going to happen?

Ms Bennett: No, we did not.

Senator FIERRAVANTI-WELLS: As part of your purview, you obviously keep an eye on listings and it is something that you are very conscious of. Was there any chatter at all before the cabinet meeting on 21 February that listings were under threat?

Ms Bennett: Absolutely not.

Senator FIERRAVANTI-WELLS: Are your discussions purely with health officials or finance officials as well, or are they generally across government?

Ms Bennett: They are across government, but they are mostly with health officials. We certainly did not have any discussions about this, and we were not aware that this change in policy was going to be put forward.

Senator FIERRAVANTI-WELLS: Have you had discussions with health officials since then?

Ms Bennett: Yes, we have.

Senator FIERRAVANTI-WELLS: Have you been given any explanations other than those in the public arena?

Ms Bennett: No. We have expressed the concerns. Just to explain, initially we remained neutral on this issue because we wanted to gauge what our members' thoughts were about this. It became very quickly apparent that people were very concerned and outraged—I think that is probably a more appropriate word. We had calls and emails from members who were just very upset about the decision and the precedent that it set. We put that to the department officials. We said it was likely to be an issue that we would need to take up and that we would certainly be talking to government about the concerns that our members had raised, but we were not given reasons other than the reasons that have been canvassed in this inquiry and put in the public arena.

Senator FIERRAVANTI-WELLS: Are you any wiser about what the definition is of 'medicines that treat serious or life-threatening conditions where there is no alternative treatment on the PBS'?

Ms Bennett: No. I think this whole issue of alternative medicines being available is something that our members are really concerned about and really take issue with. For somebody who has a particular condition and who cannot take one of the existing PBS subsidised medicines and yet there is another one that has been deferred that could potentially benefit them, to say to them that there is an alternative available on the PBS and that they should just be taking that one is very simplistic. In terms of people's quality of life, it is simply not the case that there are alternatives that are necessarily viable for all consumers. I think there was a discussion this morning along those lines.

Senator FIERRAVANTI-WELLS: When I first started this hearing and asked the question about cabinet sitting in judgment on life-and-death matters, I was howled by other members but it is very clear from the material that has come out in the survey that it is a very genuine concern. Those surveyed and those who have expressed opinions to you are very concerned about this; it is a real issue.

Ms Bennett: It is a real issue for our members, yes.

Senator DI NATALE: The government obviously argues that this is not really a departure from past practice and that there have been a couple of examples of where products have been deferred or not listed. Do you see this decision as a significant departure from previous practice?

Ms Bennett: Yes. Actions speak louder than words. There have been two instances in the past in which drugs have been deferred when they have been given a positive recommendation by the PBAC. At the point that you suddenly say, after one PBAC meeting, that seven medicines and one vaccine are being deferred, that is a change in policy, I would argue. That is my definition of a change in policy. Certainly, for consumers, it is the actions that matter. It is not what we say is policy; it is what actually happens.

Senator DI NATALE: I am interested in the response from your membership. I imagine the response has largely been around the process and so on, but have you had any responses from particular individuals or groups about any of the specific deferrals?

Ms Bennett: Yes, we have. We have had both. I cannot remember a single other instance in which you could get 60 consumer health organisations agreeing and condemning any particular policy decision; it is just not something that consumer health organisations band together to do unless there is significant concern. Many of those groups were not affected by the first seven deferrals, and for them it was an issue of the precedent and the whole concern around the politicisation of the process that it represented. It was not about the specific drugs. However, some groups did make representations to us about the impact that these decisions would have on their members.

Ms Wise: We also had responses to our survey on some individual drugs, including Prevenar 13, Invega Sustenna and Targin.

Senator DI NATALE: Did any one drug stand out as eliciting the biggest response?

Ms Bennett: I think Invega Sustenna, the schizophrenia drug, did, 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.

Ms Wise: And even if we move past those specific issues, 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.

Senator DI NATALE: I take your point about the unique ability of the government to unite 60 consumer groups, not to mention pharmaceutical companies and a range of other stakeholders, all on the one issue. But at the heart of it lies the question of sustainability around the PBS and, while I understand there are different views on how sustainable the current system is, do you have any suggestions or thoughts about improvements that could be made to the sustainability of the PBS?

Ms Bennett: I think that over many years health ministers and the department of health have canvassed various policy options. We have seen in recent years the therapeutic groups policy. We have seen the MOU recently signed. There are various ways that you can apply a policy that will reduce costs to the PBS in the longer term that do not involve compromising consumers' access to essential medicines or politicising that approach and making decisions that are not transparent to consumers. I think there are many options that could be canvassed. There are many options across the health system that could be canvassed. It may not be appropriate to talk about them now, but there are many programs that are funded that you could quite reasonably argue are not cost-effective programs. This is one that is. This is one that is the cornerstone of health care for Australian health consumers. It is not an area that consumers want to see compromised in any way. There are alternatives, I would argue, not just across the PBS in terms of the policy options there but across the health sector and the entire government program. I think that this is a program that has demonstrated its worth. There is a process that has been shown to be incredibly effective over many years. We are the envy of the world. Why would we compromise providing quality cost-effective drugs to Australian consumers who desperately need them?

CHAIR: I have a couple of questions. We have had some people dismiss different new medicines that are listed particularly on cost-minimisation basis 'me toos', which is a shorthand way of saying, 'They're from a similar class of medicine but they're a different chemical entity.' It is important to consumer groups that there be multiple medicines and multiple chemical entities within the same class because the population level health data may not capture variants in its activity or usefulness with individual patients—is that not the case?

Ms Bennett: That is the case and also, I suppose, having the clinical choice is also valuable for consumers. I think there was an example this morning around the IVF drug Synarel whereby some programs only offer one particular option to consumers. Having the other option available, while it might be an alternative and already on the PBS, if it is a subsidised option that is available and you happen to be attending a program for which the clinician has recommended the subsidised option or the non-subsidised option, that makes a big difference to

health consumers. Having more options available doesn't increase the cost; it just increases the pool of choice that is clinically available. Quite rightly, I think it provides the range of options to consumers that they can—

CHAIR: From a patient level, moving to a model where we only had maybe one or two chemical molecules out of whole class of medicines, whether they be, for example SSRIs, statins or various blood pressure medications, as some have described New Zealand, would mean there would be a substantial number of patients who would be worse off because they would not have access to the full range of what potentially might be more effective for them individually medicines.

Ms Bennett: I suppose, in terms of containing the cost to the PBS, that is probably the case to some extent anyway because we are never going to have the full range of options available. By definition, it is true that having more options available to consumers does increase the choice that is available to them, and the options that they have for not only getting access to effective treatments that treat their individual circumstance but also subsidised treatments.

Senator FIERRAVANTI-WELLS: I just wanted to follow on on some of my questions which were picked up by Senator Di Natale's point about sustainability. We are talking here about $25 million over four years—$100 million—in terms of patient care. Considering that equity and picking up the point we made earlier considering the billions that have been wasted by this government, again, that was emerging, was it not, from the material that was coming back from your consumer groups?

Ms Bennett: I suppose to consumers the savings that would be made from these deferrals seems like a drop in the ocean when you consider the total cost of the PBS program itself or the health budget. It seems that we are quibbling over a very small amount of money for what consumers see huge benefits from in terms of their quality of life, their capacity to access quality medications and all the savings that those drugs will bring. Of course when the PBAC takes into consideration whether these drugs should be listed on the PBS, it takes into account the savings as well to government. Those savings seem to have been dismissed as being less significant but to consumers all of those things are incredibly significant and it does seem like a small amount of money to save in the short term when there are such great benefits from having those drugs available to Australian consumers.

Senator FIERRAVANTI-WELLS: Clearly, Sustenna, the schizophrenia drug, was a classic example, according to some of the evidence that has been given, of providing conservative savings in relation to hospitalisation?

Ms Bennett: Yes.

CHAIR: We are closing off now, to keep on time. Thank you, Ms Bennett and Ms Wise. If you have any further information following today's questioning, could you provide that to the secretariat within about a week or so to allow us to conclude the report. Thank you for your time and your submission.

Ms Bennett: Thank you.

HINDSON, Ms Renee Louise, Member, Brain Tumour Alliance Australia Inc.

PITT, Mr Matthew David, Chair, Brain Tumour Alliance Australia Inc.

STRANGMAN, Mr Denis, Secretary, Brain Tumour Alliance Australia Inc.

STUBBS, Mr John William, Executive Officer, Cancer Voices Australia

[14:00]

CHAIR: I welcome you to the hearing. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee has your submissions. I now invite you to make a short opening statement, at the completion of which I will invite members of the committee to put questions to you.

Mr Stubbs: I thank the Senate for inviting me to speak at this hearing. We are an independent organisation, whose members are predominantly volunteers. I am employed on a point 8 basis. We work to ensure that the voices of cancer patients are heard at the national level. We have partnered with the Consumers Health Forum and Pain Australia on this matter. We have just heard Carol Bennett talk about the partnership that involves some 60 health organisations. Many of our members are still receiving treatment. Others are well past the five-year point and I am one of those. Others whose treatment has stalled may be eligible for clinical trials that are assessing the viability of new and improved targeted therapies. The issue we are addressing today is not just about medicines and money; it is about proper process, transparency and clinical based evidence that supports the introduction of these valuable new treatments.

The current chair of the PBAC, Professor Lloyd Sansom has, in past years, provided consumer organisations with the opportunity to offer their stories in the form of patient impact statements, a most transparent process which gives his committee access to real patients' stories. To her credit, though, the minister has been approachable on this issue, but we still need to see the evidence for the cabinet decision not to list those medicines recommended by the PBAC. This comes back to engagement and transparency.

There has been considerable media coverage in relation to this matter purely as a result of public submissions —another example of open and transparent engagement. We do seek good policy engagement at all levels to ensure that the best available medicines and treatments are available to cancer patients in this country. These decisions are to be based on engagement, transparency and, most of all, on evidence.

I have played a lot of AFL in my time, but all teams played by the same rules. These have been well documented and the teams—and I talk about the PBAC, the TGA, Medicines Australia, CHF and cancer organisations—all worked within these rules. We need the umpire to now say why these rules have been changed. Thank you.

CHAIR: Mr Strangman, do you wish to make an opening statement?

Mr Strangman: I will defer to our chair, Mr Pitt.

Mr Pitt: I will just make a brief opening remark and touch on the paragraphs that I had prepared but will not go into detail. There appears to be a growing emphasis in the federal health system on the most common form of illnesses and a comparative neglect of the less common illnesses and all those that are not preventable through lifestyle changes. The action of the health minister or the cabinet in vetoing or delaying the PBAC decisions to approve listing on the PBS looks set to exacerbate that situation. I have to say that a lot of brain tumour patients, as well as their families, are quite concerned about the implications of this on our group.

With respect to term of reference (i): 'any other related matter' I do have some remarks on the PBS per se, on its operations. I also have a few suggestions on how the PBS could be changed, irrespective of ministerial and cabinet discretion. I have a few suggestions about that, too. I will not go into detail here; I will just touch on them.

One thing I would like to discuss further is: is there enough emphasis on improved quality of life for brain tumour therapies, particularly in light of the decision recently to not list avastin for glioblastoma, which is a grade 4 brain tumour, the most malignant type of brain tumour? The PBAC decision against listing a medicine does not

appear to me to be particularly transparent. I think the applicant receives the report, as well as the minister, but consumers are not given the full details of the report.

We are also concerned about the reliance on or requirement for phase 3 clinical trials in the PBAC process as the only acceptable evidence. As a small cancer type with over 120 different types of brain tumours and small numbers of patients, it is very hard to get a phase 2-3 clinical trial for every subtype of brain tumour, so we are never going to get the evidence for a lot of patient types. This problem is particularly notable for not only the PBS but also the MBS and new approaches. For example, FET-PET neuroimaging, endoscopy techniques and intraoperative MRI are not really amenable to a phase 2-3 type clinical trial approach.

We have Renee here who can speak more on the topic of the rigidity of listings for the Pharmaceutical Benefits Scheme, in particular in the case of glioblastoma, temozolomide and anaplastic astrocytoma. Just to describe it, anaplastic astrocytoma is a grade 3 brain tumour, which is the second most malignant type of brain tumour; grade 4 is blioblastoma multiforme. Temozolomide is currently approved for initial therapy for glioblastoma multiforme patients but is only approved for recurrent anaplastic astrocytoma patients. Phase 3 clinical trial data was published two years ago by Wick et al and showed improvement for anaplastic astrocytoma patients taking temozolomide as a first-line treatment. That is a general comment about the rigidity of listing on the Pharmaceutical Benefits Scheme as it currently stands. It does not have a lot of bearing on the ministerial discretion that we are talking about today.

In the previous submission you talked about options to make the Pharmaceutical Benefits Scheme more cost-effective without impairing a patient's access to life-saving and life-improving pharmaceuticals. One option which other countries have taken up—for example, America, in the case of avastin—is to conditionally approve a medicine, pending the results of a definitive phase 3 trial. As I said, that is happening with avastin in the AVAGLIO trial. We would recommend that the government considers doing such activities in Australia. A promising phase 2 trial result or a phase 1 trial result is not enough to get a PBAC approval for a condition like a brain tumour, which has not seen a lot of improvement in five-year survival over the past 20 years, where they get conditional approval pending the final results. I will hand over to Renee and Denis to talk more about that.

Ms Hindson: I was diagnosed last year with an anaplastic astrocytoma. I had surgery to remove the tumour. I had surgery in Sydney followed by radiation in Canberra. My Sydney neuro-oncologist recommended radiation and chemotherapy. At the chemotherapy stage, I was informed that I did not qualify for the drug under the PBS and that it was going to cost me $3,000 a month, which does not seem like a lot, but I am a single mother of two young children and the drug would certainly be life extending for me. It was a very stressful time. I went through many avenues trying to find funding for the drug, through compassionate programs and through the drug company directly. Eventually I did get hold of the temozolomide through the hospital, at a subsidised rate, but, in the process of getting to there, I missed out on getting in on a clinical trial because of the poor handling of my case between the New South Wales and ACT health systems. I sort of slipped through the cracks and missed the window of opportunity to get in on the trial, which had to be before I had the radiation.

Given that anaplastic astrocytoma is about four per cent of primary brain tumours, which is 1,400 year in Australia, there are just not enough people in my position to participate in clinical trials, and the information is not there yet to get that listed. But people should not be put through what I have been put through for the last seven months.

CHAIR: Thank you. Do you have any questions, Senator Polley?

Senator POLLEY: Evidence was given on Thursday and has been given throughout today in relation to the change in the process whereby cabinet makes the final, arbitrary decision on what drugs will or will not be listed on the PBS after being recommended by the PBAC. The process has not changed other than there is a threshold of $10 million which has been removed, but the process itself, how cabinet arrive at their decisions, is still the same as it was previously. There has been no evidence to suggest there were any arbitrary written criteria previously, anymore than there are today. What I am asking you, as advocates for the community, is: there has been criticism, as I said, and the politicisation of the process now; why should consumers have the right to be part of the PBAC process and yet not be able to be part of the cabinet process?

Mr Stubbs: It is an interesting question. The government has engaged a lot with advocate groups, and I have been involved with the PBAC and the PBS over the last three years as part of a consumer group talking about drugs and access to drugs and the transparency of the whole process. We believe that the PBS section of the department and the PBAC are listening to what consumers want. We are aware of the $10 million threshold and we are certainly aware of drugs not being listed from time to time. There are a number of cancer drugs that fall into that process. It appears, in the feedback that we are getting, that it has been an arbitrary decision by either the

minister or the department not to go ahead with this bulk funding. Therefore the transparency, we believe, has somewhat ended. We do believe that the rules in some way, shape or form have been changed.

This is the major concern, especially in relation to the 'me too' drugs. There were some drugs listed as part of the decision that you could use one against the other. If you look on the TGA website, you will find that that is not the case. So here we have two well-regarded—not only nationally but internationally—authorities: the PBAC, led by Lloyd Samson, and the TGA, who put forward these rules and regulations. The economic analysis is done. All the efficacy and all the evidence is there, and yet the decision is made not to go ahead with it. I suppose it comes down to perhaps some of it being rubberstamping, or the assumption—maybe that is where we are wrong—that some of these drugs will be rubberstamped.

But the issue for us is that there was no engagement beforehand. We have a very good relationship with the minister's office and the department, so it does seem that it has become an arbitrary decision. If it is going to happen this time, it could also happen further down the track. I have real concerns about the downstream effects of something like this. I was a member of the clinical trials action group, which looked at ways and means of getting people onto clinical trials, and one thing is the availability or lack of availability of patient groups here. In terms of supporting what Matthew said, it is really important. With a low number of patients, we need to get clinical trials and we need to have the drugs available in Australia. If the approval process is going to be seen to be not transparent, and if it is stalled in any way, it could have real downstream effects, especially for cancer patients in this country.

Senator POLLEY: Can I also ask Cancer Voices Australia whether any of the deferred drugs were designed to treat cancer.

Mr Stubbs: Erbitux has been delayed, but that has now been put in. There is one drug, Fragmin, which could have been used for cancer patients with lymphoedema. But it is not about cancer drugs; it is the process and the transparency of the process that we have real issues with.

Senator POLLEY: Do you have an indication of how many drugs for treating cancer have been listed on the PBS this year?

Mr Stubbs: There have been a number of cancer drugs, certainly.

Senator POLLEY: I want to go to Brain Tumour Alliance Australia. In your discussion you referred to a rejection of a drug that would have been beneficial. Was that a rejection by the PBAC rather than a deferral by cabinet?

Mr Pitt: That is correct.

CHAIR: Obviously, with the small number of patients, clinical trials are particularly important for cancer medications more than most because of the way that extra indications can work for new medicines and the way that impacts on the PBS subsidy. Is it a concern of any of you at the table that delays in bringing medicines to the market for some indications will actually delay their use in clinical trials for other indications? In my experience, doctors tend to try trials in new areas when they are familiar with a medicine in the first place. Is that one of your concerns about the potential lack of access to newer cancer medications?

Mr Strangman: Yes, that is definitely a concern. The brain tumour environment is a very fast-moving environment. As Matt explained, glioblastoma is a grade IV brain tumour and it replicates itself every 24 days. So we are on a time line compared to other cancers. We need to be at least 50 metres in front of the starting line in a 100 metre race—if I can use that analogy. We just do not have time to waste. Therefore, we are concentrating on part (e) of your terms of reference, 'any other issues'. We are hoping that in your report you might come up with recommendations about how certain things could be improved. One thing we would say is that, in regard to the less common cancers, there should be greater flexibility and new measures should be taken on board that would facilitate patients' access to promising new therapies. For the benefit of the committee, I would just like to flag that this is a problem that both New Zealand and the United Kingdom are grappling with at the moment. A colleague of mine in the United Kingdom sent me an email overnight referring to how they are trying to do it. This is from the Rare Cancers Forum in the United Kingdom. It says: 'The Cancer Drugs Fund is an evaluation of the impact of policies to improve access to cancer treatments. Over 2,500 cancer patients have had treatment provided through the Cancer Drugs Fund.' So their way of looking at it is a special fund to give access to patients to these promising new therapies. New Zealand also—surprisingly, because I heard some earlier evidence that New Zealand had this history of PHARMAC being very antipathetic to approvals—created a new pathway. I quote from the *Pharma Times* of 7 July:

PHARMAC 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.

The new arrangements - which are expected to increase the Exceptional Circumstances scheme spending from NZ$4 million now to around NZ$8 million in the first full year - have been introduced …

So there are two interesting things. It seems to me that other jurisdictions are recognising that the kind of slow, evidence based medicine, phase 3 clinical trial, efficacy approach just is not a size that fits all.

CHAIR: Mr Pitt, you alluded to a concern or an observation about the focus of health policy increasingly being illnesses or ailments that are common and those that could be addressed by lifestyle changes. One of the concerns raised about this approach by the government to defer the consideration of medicines without any guidelines around it is that it exposes the process to greater risk of political or lobbying interference. Given the concerns that you raised at the start of your opening statement that you are representing a group here that is a very small number of people in Australia, are you concerned that this approach would further push you out of consideration because you do not have huge numbers behind you?

Mr Pitt: Absolutely. In this sort of might is right type system brain tumour patients will always lose. Unfortunately the people who do have brain tumours tend not to stay around in advocacy for various reasons, not least is the morbidity and mortality and also the trauma caused by it. Even given our numbers we actually have a reduced political power and a reduced presence because of the impact of the disease on families. We are doubly afflicted. Yes, that would be my general concern.

Senator FIERRAVANTI-WELLS: In terms of both of your groups, can you give me an idea of your memberships?

Mr Stubbs: We have state member organisations, with New South Wales being our biggest. There are in excess of 4,000 in New South Wales, 800 in Victoria, South Australia, which prides itself as being the cancer riders group, has in excess of 800, WA has around 100 and Queensland has around 200.

Senator FIERRAVANTI-WELLS: So it is about 6,000 all up around Australia.

Mr Stubbs: Yes. These are all cancers. We also liaise and link very strongly with the individual cancer groups—Breast Cancer Network Australia, Leukaemia Foundation, prostate cancer. So we do partner with them on the broader cancer issues.

Senator FIERRAVANTI-WELLS: Mr Pitt, your organisation is 60 organisations?

Mr Pitt: I will let Denis answer.

Mr Strangman: We are a relatively small group. Brain Tumour Alliance has about 60 members throughout Australia. I happen to know precisely how many people we have on our books as contacts, 528, because I did a mail-out yesterday. We are a loose organisation mainly operating through our contacts in all states.

Senator FIERRAVANTI-WELLS: Given the nature of the cancers that are involved, we are talking about a relatively small group of people. I think brain tumour is one of the fastest growing in terms of cancer groups. I have experienced it through a close friend of mine who was recently diagnosed and given a relatively short period of time. We are really only talking in most instances of months, Ms Hindson, before you are actually able to react and get appropriate drugs.

Ms Hindson: Yes.

Mr Strangman: Renee is going to be the exception. She will live for years and years and outlast us all.

Senator FIERRAVANTI-WELLS: We wish you all the best. Mr Stubbs, I think you mentioned that when you are dealing with cancer you talk about the first year, the second year, the third year and the fourth year until you get to that magic five years. But for many cancer patients the prospect of new drugs is so vitally important. Unlike perhaps a lot of other things, new drugs coming on the system are vitally important.

Mr Stubbs: Yes. I am 10 years post a bone marrow transplant. I have not been on drugs for the last nine years so I am certainly one of the very lucky ones. Somebody talked about the cost of cancer. I did a talk at the Clinical Oncological Society of Australia, COSA, two years ago. Cancer has cost me half a million in terms of loss of income, out-of-pocket expenses et cetera. I am not seeking recompense but that is an example of somebody who is educated and middle class—all of those issues. I have been able to absorb those costs, but for someone on lower incomes, they just cannot do it. They have to make decisions around drugs or family and most people will say family and forsake drugs.

Senator FIERRAVANTI-WELLS: I do not know whether you heard the previous evidence about the concerns about the development of a two-tiered system. That is what we will end up having. Those who can

afford the drugs will be able to access them and those who cannot afford the drugs will not be able to access them and will suffer the consequences.

Mr Stubbs: Unfortunately, that could be the case. I am also a member of an international colon cancer consortium. The health system in this country is incredible when we compare it with what happens in other countries. It is something to be very proud of and we want to continue that. I am lucky that I had leukaemia in this country. We want to support our clinicians in giving the best possible access and treatment to all patients in this country.

Senator FIERRAVANTI-WELLS: Senator Polley talked about X number of listed cancer drugs but given the diversity of cancers diagnosed in Australia, new developments are vitally important to deal with the diversity of cancer. So simply saying, 'We've listed 10 cancer drugs this year and that covers all the cancer drugs,' is not an accurate reflection of the situation, given the diversity of cancers that are out there.

Senator POLLEY: You are misrepresenting the intent of my question.

Senator FIERRAVANTI-WELLS: No, I am just drawing the inference—you said that X number of cancer drugs were listed. I drew the inference from that that is quite a number. The point I am making to Mr Stubbs is, given the diversity of what we are dealing with with cancer, it is vitally important that those drugs and anything else which becomes available are vitally important.

Mr Stubbs: I think that is true. Cancer is going to fall more and more into the target of therapies because cures for cancer or the ability to control cancer and put somebody back into the workforce will have a significant impact on a population. Going along with what Mr Strangman is saying, maybe there has to be a better way to fund or to look at what is going to happen in the cancer arena and the indications around cancer drugs.

Senator FIERRAVANTI-WELLS: You made comments and obviously your concerns are in the general part in your submission. We took evidence the other day from the Australian Pain Management Association—I am not sure whether you are aware of their submission. They made a comment that it is estimated that less than 50 per cent of patients have effective pain relief and a similar number of patients with acute pain failed to receive effective pain relief. While your submission is in the general, would you comment in particular on the opiate-based medications and potential benefits?

Mr Stubbs: There was a national pain summit held in Canberra, I think two years ago, and cancer pain was not on the agenda. We were able to get cancer pain on the agenda because a lot of people following cancer treatments suffer pain. I mean, you look at women who have had mastectomies; they suffer incredible pain. If they do not get access to those drugs, where do they go? They go back into hospital, at $1,000 a day or whatever it costs for hospitals. Those downstream effects, and the impact on the health system, and the impact of those costs, need to be controlled. Targeted therapies are possibly one way of getting that, because they keep people out of hospital. Many patients who have gone through cancer have carers, have a good family base, or have access to organisations who can perhaps fill a bit of a gap. So I think that may be one way around looking at the situation.

Senator DI NATALE: Thank you all very much for your submissions and thank you also for paying attention to the issue of ways of getting listings for products that affect small numbers of people; I think that is a very challenging problem and something that needs to be addressed. One of the questions that came to mind from the submission from Brain Tumour Alliance Australia was this statement:

By not listing these medications and so denying people access to them through the PBS, doctors are forced to prescribe other medicines that may even be more expensive but already subsidised through the PBS.

Do you have any examples of where that has happened?

Mr Strangman: On reflection, I do not think that, in our particular instance, brain tumours, we would hold to that. I was discussing it with a colleague on our national committee before we came here. Take, for example, Renee's case, where she was prescribed temozolomide which, without subsidy, can be very expensive—$3,000 a month. What would happen if she were unable to access that is that she would be prescribed a much older alternative therapy—vincristine, or something—that would be horrendously more nauseating and uncomfortable to her, but which, I would have to admit, would not be more expensive than the temozolomide.

Senator DI NATALE: I can envisage other areas. But thank you for that. The other question is around low molecular weight heparin. Do you have a sense of the numbers who would be affected by that? I know it is a bit tough—

Mr Stubbs: No, but I can find out and report back to you.

Senator DI NATALE: I would just be interested to know the magnitude of the saving that would be envisaged from the deferral of that listing.

Mr Stubbs: The one I have referred to in my submission?

Senator DI NATALE: Yes.

Mr Stubbs: It is not so much about numbers; it is about the process. Here we have two drugs. One is recommended by the PBAC to have a different quality from the other drug, and so we believe it is probably not a me-too type drug. This is public information on the website which would be available to the cabinet and the government.

Senator DI NATALE: I certainly understand that, and I think sometimes it is just good to get a sense of the sorts of numbers we are talking about. I think people are less inclined to support a change in process when they see that the magnitude of the problem that is being addressed is much smaller than might originally have been conceived. But I take your point. Would you all regard this as a significant departure from current process? I know the argument was put earlier today when the Department of Health stated that there were precedents for this. Do you all regard this as a significant departure from what has happened previously?

Mr Stubbs: With our number base—it is around 6,000—I would say that there were probably 300 people on the line almost immediately. So it did gather momentum. We first wrote to the minister on this on 14 March, and that was our concern; we believed it was a change in policy. And also linking it with the possible downstream effects, the access to drugs and clinical trials, and the whole government agenda around the PBS and the PBAC, we did believe, was a departure from normal policy.

Mr Pitt: From the perspective of brain tumour patients and caregivers, who BTAA seeks to represent, there were not any drugs related to brain tumours deferred, but 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.

Senator POLLEY: I would like to correct the inference of Senator Fierravanti-Wells' interpretation of my question. As somebody who has a very close family member with brain tumours who is coming to the end of their life, I find that offensive. Would it be your preferred position that everything that is recommended through the PBAC is—

Senator FIERRAVANTI-WELLS: Chair, on a point of order, I ask Senator Polley to withdraw that.

CHAIR: Senator Polley, I have a point of order from Senator Fierravanti-Wells.

Senator FIERRAVANTI-WELLS: That was not my intention, Senator Polley. I think you should withdraw that comment. I think if we are going to go down that route, I think you understand why I was asking—

CHAIR: Senator Fierravanti-Wells, are you taking offence at the inference that Senator Polley said she drew from your question?

Senator FIERRAVANTI-WELLS: Yes.

CHAIR: Senator Polley, are you going to withdraw?

Senator POLLEY: No, I am not going to withdraw. The inference was very clear.

CHAIR: Senator Fierravanti-Wells, I will give you a chance to respond in a second before we conclude.

Senator POLLEY: In relation to the process whereby cabinet makes the arbitrary or final decision after being recommended from the PBAC that a drug be listed, would you prefer that there was an automatic stamp of approval for every drug that is recommended by the PBAC? Is that a process you would prefer over the one where the cabinet makes the final determination about the PBS? Have you been given any commitment from the opposition that they are going to change their policy by automatically approving every drug to go on the PBS that is recommended by the PBAC?

CHAIR: First of all, I will clarify for the witness: it is not a court. You do not actually have to answer any question put to you in the terms that it is put. I will address some of the things that Senator Polley said in a second.

Mr Stubbs: I know nothing about the second part of what the senator was talking about in relation to the opposition. No, I do not believe that we can expect every drug to be rubber-stamped; however, when there are a large number of drugs that are rejected on the one occasion which fall within—

Senator POLLEY: They were deferred and not rejected.

Mr Stubbs: Sorry, deferred, but fall within the criteria, that raises the alarm bells. I think that is what most of the people in the submissions have been talking about.

CHAIR: I will not bother addressing the allegation about the opposition that Senator Polley referred to, but I will give Senator Fierravanti-Wells an opportunity to correct the record, given that she raised an objection to something Senator Polley said.

Senator FIERRAVANTI-WELLS: I will just say Senator Polley asked Mr Stubbs a question in relation to the number of cancer drugs that had been listed in a particular year. The inference that there had been X number of drugs meant that there was a surplus or a large number of drugs put on the market in relation to cancer. That was the point I was seeking to address, Senator Polley. I think we have all had experiences with cancer and those sorts of issues so that was purely the point that I was trying to make and, in so far as, Senator Polley, your comments went outside that I would ask you to withdraw them.

CHAIR: I do not think the comments were unparliamentary, so I cannot insist upon their withdrawal but, Senator Fierravanti-Wells, you deserve the opportunity to correct the record. I thank Ms Hindson, Mr Strangman, Mr Pitt and Mr Stubbs for your appearance here today and for your submission. If you took any questions on notice or would like to give us further information, I would ask that you try and do that within a week or so to allow us to come to a conclusion with the report.

Proceedings suspended from 14:39 to 14:53

HOCKING, Ms Barbara, Executive Director, SANE Australia

Evidence was taken via teleconference—

CHAIR: Welcome. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee has your submission. I invite you to make a short opening statement, at the conclusion of which I will invite members of the committee to put questions to you.

Ms Hocking: I appreciate the opportunity to present to you, even as a disembodied voice! I will just speak very briefly to the submission that we put in earlier. SANE Australia are a national charity working for a better life for people affected by mental illness, and we very much value the PBS system because it provides easy access to good medications, which are the cornerstone of treatment for most mental illnesses. As a general rule we do not recommend any one particular treatment but, in this instance, our submission had particular reference to the impact of the non-listing of paliperidone, the Invega Sustenna injection. Our reasons for that are that we believe that there are major advantages for people with illnesses like schizophrenia in having access to this newer monthly long-acting monthly injection in the arm rather than the fortnightly injection in the buttock. The timeframe is very important, and while it is very hard to quantify the cost savings of the dignity of someone receiving an injection in the arm rather than the buttock, I strongly believe that it has some major consequences, but it is something that would be very difficult to put a dollar figure on. However, having the monthly injection does make adherence more likely. It also reduces by half the number of visits to a doctor or other clinician to get the injection. It also means people may be more likely to attend the appointment, and it certainly also frees up the family or other carer who is involved in providing day-to-day support. One of the things that we did not comment in the submission, but I know makes a difference for clinicians, is that it is much easier to administer as well. I think that not having a coal chain does bring about some cost savings, as does having the administrative burden of less frequent injections. I think that savings to the health system are really important.

In terms of the financial impact on the budget there will be others much better qualified to comment on that. One thing we are concerned about is that the cost to patients will be reduced because they will have fewer prescription charges and the costs associated with that when they are receiving the injection. Even though it is $5.60 for filling a script that is actually a major disincentive for someone who is on a low income and who has very, very little disposable cash.

Other than that I think I will leave my comments, with one final exception, which is to say that to change the process of a system that has been working very well with this recent decision for every recommendation to go through the parliamentary process is, I think, something that does concern us. We believe that the committee members on the PBAC have been entrusted to do this, and it would be good, freer, quicker and much more efficient, probably, to take their recommendation for these medications.

CHAIR: Thank you, Ms Hocking.

Senator FIERRAVANTI-WELLS: I am not sure if you are aware of evidence that was given the other day in Melbourne. Potentially we are talking about 100,000 people or thereabouts who suffer from schizophrenia and, in relation to this medication, the savings are minor. We are talking less than $5 million over five years compared to the cost of hospitalisations, which have been estimated for the potential number of users to be over $52 million.

Ms Hocking: Yes, I can well imagine that. Certainly what may seem like an initial cost can, in fact, be a very important long-term cost saving if it does mean that someone is getting the most effective treatment for them. And it is such an individual thing if it means that that person would have fewer hospital admissions and may well then get back to work and contribute through a pension. So the initial cost can very often lead to major cost savings.

Senator FIERRAVANTI-WELLS: For the record, what is your membership?

Ms Hocking: We are not a membership organisation in the sense that many other groups are.

Senator FIERRAVANTI-WELLS: What are the number of people that you, basically, assist?

Ms Hocking: I would put an estimate through the distribution of SANE News and the Helpline contacts we have from people that it is in excess of 15,000. Many of those are people who then have further contacts themselves.

Senator FIERRAVANTI-WELLS: Have quite a number of people approached the organisation following this decision?

Ms Hocking: Certainly. I do not have the actual numbers, but certainly we would have had a number of emails and calls to a helpline, telephone inquiries asking about that. There is a lot of fear from people who believe

that this decision may then spill over into other areas and that there may be an increasing restriction and choice available to people.

Senator FIERRAVANTI-WELLS: Your experience in the past has been—and you make reference here to the way the system has been working for a long time—a much more routine way of decisions involving less than $10 million basically being dealt with by the minister in a much easier and more timely manner.

Ms Hocking: Yes. It seems to have been working pretty well up to now. This current example or situation that we are in has certainly highlighted for us the potential for a real politicisation of the process. That is concerning because it then advantages people who have stronger advocacy groups behind them. Certainly, it is a time-consuming business which may be a chore for some people but, for people who need these medications, it really adds an increasing disability to their lives and a lot of distress.

Senator FIERRAVANTI-WELLS: With people suffering from mental health issues, medication and taking medication is a difficult issue to start off with, so anything that makes it a lot easier is obviously very beneficial?

Ms Hocking: Definitely. Certainly, no-one wants to have to take medication long term. It is not an exclusive thing for people with mental illness, but certainly if people are sometimes unable to recognise that they need medication as part of the symptoms of their illness it is really important that we have the most effective and least intrusive way to provide the benefits of that medication to them.

Senator FIERRAVANTI-WELLS: Obviously, from the perspective of this medication, for those people who live in regional and rural areas who have difficulties in accessing medical services, it will halve the time they need to travel to access those services?

Ms Hocking: Very definitely. If you have a monthly visit rather than a fortnightly one, that gives you much more time that you can spend on other areas of your life rather than on travelling, which could be a very tedious and costly process for people. So it is not just about the cost of the extra script; it is also about the cost of travel to your doctor to get that script and the more isolated you are, then the longer it takes to travel and the more costly it becomes.

Senator POLLEY: Thank you very much for your submission. I have a couple of things. From what I can gather, from having been briefed, in time past cabinet sometimes took years to make a recommendation on some drugs going on the PBS. I do not think the change that the government has implemented, by removing the $10 million barrier for cabinet to consider and to make the final decision, will disadvantage consumers in the long term. When you talk about the politicisation of the process, how has that happened as opposed to previous cabinets making decisions on what goes on the PBS after recommendations by the PBAC?

Ms Hocking: I can only really talk about the lower cost medications, the ones where there was an automatic process. Certainly, I cannot comment on the much more costly medications and the political process that may have been involved in those. Certainly, the PBAC makes its decisions on the efficacy of the medication and then the cost benefits. I would have thought that, for the lower cost medications, that would have been enough to be streamlined. The number of people with long-term schizophrenia who may need this medication is actually quite small. Many more people are benefiting from oral medication that will have a different cost. I am not saying it is a lower cost.

Senator POLLEY: You made some comments in relation to your perceptions that this might have ongoing effects on other medications. What evidence do you have of that?

Ms Hocking: I do not have any evidence for that at the moment; it is just a sense that I have. This process takes a lot of time and a lot of energy, not just at your end but also at our end. It was worrying that this may be another stage in the process that would slow things down and keep everyone very busy.

Senator POLLEY: The process has not changed. The PBAC makes a recommendation to government, and a decision is made by cabinet. Drugs cannot be listed on the PBS without the recommendation of the PBAC. Is that correct?

Ms Hocking: That is my understanding, yes.

Senator DI NATALE: I have looked at the individual drugs that have been listed, and this is the one that puzzles me the most. Paliperidone is essentially metabolised to risperidone. Is that correct?

Ms Hocking: I am not a clinician, nor am I a pharmacist, so I cannot talk with any authority about the pharmacology. Your understanding is probably much superior to mine on that one.

Senator DI NATALE: Okay. The point I am trying to make is that the only real difference between that and the currently available drug is the different schedule for injections. This new drug would replace the two fortnightly injections; you basically drop an injection. Is that right?

Ms Hocking: That is one aspect of it. The other aspect is that it is much easier to give and receive: it is a medication that you can take in the arm, as opposed to the buttock. It is also a medication that does not require a cold chain, so its distribution around the country is much simpler and easier.

Senator DI NATALE: it is essentially going to replace an existing medication. I cannot see why, in most instances, this would not replace what is currently available, for the reasons you have just given.

Ms Hocking: It may well replace—

Senator DI NATALE: I am trying to establish the increased cost associated with this medication. How much money is the government going to save as a result of listing paliperidone?

Ms Hocking: I cannot give you a figure for that; I would hope that the committee has access to that already. In my understanding, it is not going to be much more expensive for the country. But I think it will be more expensive for the person using the medication to have to have a fortnightly one rather than a monthly one.

Senator DI NATALE: You may not be able to answer this question, but you may be able to give an opinion on it. Given that this is unlikely to pose a significant additional cost over the coming years, can you see any obvious rationale for not listing it?

Ms Hocking: None at all. I think that if we have this one as a choice, just as you suggest, it may be that it will replace the previous one. I do know that some people feel that, pharmacologically, there are some differences. But, even if there are not, it does appear to be a superior delivery mechanism, with everything else that goes with that.

Senator DI NATALE: Okay, that is fine. I am glad I am not scratching my head for no reason; it sounds like there are a few other people scratching their heads as well.

Ms Hocking: Indeed, yes.

CHAIR: Ms Hocking, Thank you very much for your time and your submission. If you wish to provide us with any supplementary information, we have about a week until we have to start finalising the report.

TYRRELL, Ms Helen, Chief Executive Officer, Hepatitis Australia

[15:09]

CHAIR: Welcome. Information on parliamentary privilege and the protection of witnesses and evidence has been provided to you. The committee has your submission. I invite you to make a short opening statement, at the conclusion of which I will invite members to put questions to you.

Ms Tyrrell: Hepatitis Australia is the national peak body for the state and territory hepatitis community organisations, which are our members. The mission of Hepatitis Australia is to ensure effective action on both hepatitis B and hepatitis C to meet the needs of all Australians. There are around 217,000 people in Australia living with chronic hepatitis C and another 165,000 with chronic hepatitis B.

In relation to the deferral of the listings of the medicines on the PBS, Hepatitis Australia is very concerned that, since February 2011, the federal government has referred all PBAC decisions to cabinet and has departed from the norm by making decisions to defer listings of drugs which have been recommended for listing by the expert committee. We note that 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.

Hepatitis Australia considers that 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. We do 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 what was a very well-established model of decision making, the government should have consulted broadly with stakeholders, including health consumers; they should have considered the consequences of any delay in PBS listings; and they should have considered the merits of other cost control methods. In addition, we consider that they should have thought more fully about the longer term implications of these changes, including the consumer loss of confidence in the government due to the politicisation of the PBS listings and the lack of transparency in cabinet decision making.

In relation to the impact on consumers, in general delays in listing of PBS medicines already approved by 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. 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.

As the cabinet process is non-transparent, it is impossible to know if the politicians who are now making these 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 only last year.

In regard to the future availability of medicines, the minister has indicated that the deferrals of PBS listings since February are temporary and they will be reconsidered at a later date, although the process for that has not been delineated. Once trust in the established PBS approval system has been lost, a level of cynicism is to be expected, particularly regarding the government's future intentions. The uncertainty and lack of confidence created by a non-transparent process for PBS listings may lead some pharmaceutical companies to reconsider whether to invest in making applications for listings of their products in Australia. This would most likely have some dire consequences for access to medicines generally throughout the community.

With regard to the cabinet criteria applied, we believe that cabinet's chief concern when deferring the PBS listings was to support achievement of the Prime Minister's pledge to deliver a budget surplus by 2012-13; however, how this fiscal imperative was applied to the decision-making process for individual medicines is a complete unknown. We do not consider that it is reasonable to expect cabinet to either have the time or the expertise to understand the highly technical evidence put before PBAC. In relation to the clinical need and cost effectiveness, we do believe it is reasonable to expect that healthcare consumers will continue to have access to

quality medicines based on an expert and a transparent system of assessment. As an organisation, Hepatitis Australia supports the governments push for transparency as part of the national health reform process and we believe that this principle should also be applied to the cabinet decision-making process around PBS listings.

In relation to the expert advice from PBAC, if this advice is to be overridden by alternative advice from other sources, it brings into question the legitimacy and the 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 one medicine and a cross against another is a complete mystery. The goalposts have not just been moved; they have gone missing, and the confidence in the process of listing medicines on the PBS has consequently evaporated.

With regard to the financial impact on the Commonwealth budget, Hepatitis Australia understands that the costs associated with the PBS and health care generally have to be sustainable into the future; however, we also note that Australia's healthcare system is not in crisis. 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 healthcare costs incurred due to poorer health outcomes in those individuals unable to access necessary and potentially lifesaving medicines? Hepatitis Australia just does not believe that the Australian government has given sufficient attention to examining those two financial impact questions.

With regard to the consultation process, 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 listings. 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 wellbeing of people in need of subsidised quality medicines.

In conclusion, Hepatitis Australia considers that the process for cabinet review of the Pharmaceutical Benefits Advisory Committee recommendations is extremely flawed and problematic and, in line with consumer expectations around transparency of decision making, we call for a return to the established process of approvals for PBS listings which was in place prior to February 2011.

Senator POLLEY: Thank you for those comments. I was wondering if you could go through for me the previous cabinet's transparent process for making decisions about the PBS list?

Ms Tyrrell: The Pharmaceutical Benefits Advisory Committee process was transparent. All consumers and pharmaceutical companies were very well aware of what criteria were applied by the Pharmaceutical Benefits Advisory Committee in making their decisions.

Senator POLLEY: And nothing has changed in that process; it is still as transparent and independent as it always has been.

Ms Tyrrell: That part of the process.

Senator POLLEY: You asserted that there is a lack of transparency in the cabinet's decision, and their responsibility to make the decision is part of the responsibility of the federal government. I was wondering if you could outline to me what the transparent processes were of those previous cabinet decisions?

Ms Tyrrell: The previous cabinet decisions only applied to those medicines in excess of $10 million. Now every single decision is being referred to the cabinet. Obviously if you only have a small number of drugs supplied to cabinet, they will have an opportunity to look at those in a little more detail than they will if they have to apply their minds to a very highly technical process that an expert advisory committee has already gone through for them. I do not know what criteria they are applying; no-one knows what criteria they are applying. It disturbs me greatly that one of the drugs that was initially deferred in February has now been listed. As far as I am aware there is no great change to the economic forecast of Australia, so what has changed between then and now? What has been the pressure brought to bear on cabinet that has made the drug be listed and not any of the other drugs? If you could tell me that I would be very happy to hear the answer.

Senator POLLEY: We had evidence given to us this morning that there have not been criteria applied by any cabinet previously for any decision that was made—whether it was over $10 million or under, which is now the policy direction the government has taken. There were no criteria applied that were written down and could be tabled here. In that sense, the process has not changed.

Ms Tyrrell: I think that is drawing a very strange conclusion to the change in process. There is most definitely a change in process. Previously there was not a referral of all drugs to cabinet; it was a routine process for most

drugs to be approved by the minister on the basis of the PBAC recommendations. Cabinet were referred some drugs and made a decision on that basis. We have not put our mind to what the criteria were. Various cabinets have been involved in that process. The Liberal cabinet process may be different to the Labor cabinet process. If cabinet are going to be referred every single decision of PBAC then I think they have a responsibility to tell us why they are approving some and not approving others. They obviously have a different criteria to their expert advisory committee. What is that different criteria? That is my question.

Senator POLLEY: The criteria that the PBAC work under have not changed at all. They make their recommendation and those recommendations are ultimately judged by the cabinet. I do not see how that has changed. Is it not hypothetical to talk about what may or may not be deferred or rejected in the future? You have no evidence to suggest that any drugs relating to hepatitis are planned to be rejected or deferred.

Ms Tyrrell: I am not here solely on the basis of our own constituents; I am here because they have expressed concerns. I am here as a consumer of the healthcare system in Australia who has grave concerns for the future of the PBS if cabinet interfere in the decision making.

Senator POLLEY: It is an assertion that they are interfering in a process. If we go back to the process by which a decision is made, every drug now goes to cabinet and that is the change to the process, but the independence of the PBAC has not changed. As the chair stated in his evidence, it has always been the case that the government reserves the right to make the final decision on what is listed. Are you suggesting that somebody else ought to be making a decision? Should everything that the PBAC puts forward be automatically listed on the PBS?

Ms Tyrrell: I am suggesting that there has been a change in the established process.

Senator POLLEY: But are you suggesting—

Ms Tyrrell: I am not suggesting that it is not cabinet's right to make the final decision; I am suggesting that in previous times, both in Liberal governments and in Labor governments, that has not been the process. There has been a change in the established process.

Senator POLLEY: Do you also acknowledge that there has been an increase in the demand on the PBS, for a range of reasons, not least of all the ageing population? Nine billion dollars is currently spent on the PBS by the government, so they have to show some financial consideration when making these decisions, along with other health considerations and programs.

Ms Tyrrell: I do not deny that cabinet have the right to make decisions broadly to ensure that the PBS remains sustainable into the future. What I am saying is that cabinet should not make a change to established processes without consultation with consumer groups and pharmaceutical companies so that they can actually hear what the consequences of their actions may be not only for individual medicines but for the future of the PBS, confidence in it and confidence in the government.

Senator FIERRAVANTI-WELLS: In terms of your membership, you are the national peak body for state and territory hepatitis community organisations, who are your members. Roughly how many members do you have? Tell me how many people in Australia have hepatitis.

Ms Tyrrell: Our members are membership organisations themselves. Our members are the eight state and territory hepatitis organisations. Within Australia, there are 217,000 people who have chronic hepatitis C. In addition we advocate for people with hepatitis B, and there are a further 165,000 people in Australia with chronic hepatitis B.

Senator FIERRAVANTI-WELLS: So when in your submission at page 4 you talk about these two new hepatitis C treatment medicines you are talking about the 217,000 people that would benefit from that drug.

Ms Tyrrell: That is correct, yes. The impact of hepatitis C varies over the lifetime. Many people are not aware at the time when they are infected, and they may have very few symptoms in the first five or 10 years of infection. If they have the infection for a longer period of time, the impact on them rises exponentially. What we have seen since 2003 is a 30 per cent or more increase in the number of people with moderate or severe liver disease. That is a real burden to the healthcare system into the future. Hepatitis C is already the major cause for liver transplantation in Australia. It has major financial and social impacts both on the individual and on the healthcare system as a whole. Currently the most difficult genotype to treat is genotype 1, and the current treatments provide a cure rate of about 45 to 50 per cent. It is an arduous treatment process; it is around 12 months and it is likened to chemotherapy continuously for that period. It can be an extremely arduous process. It is not something people undertake lightly. You have to be in the right space in terms of having supports around you to go through with that treatment. Many people are now reaching the point where they have lived with the infection for 30 or more years. Women going through the menopause often find their liver disease starts to change and get dramatically

worse, and we have a large proportion of people in that end of the demographic of people with hepatitis C in Australia. They are going to benefit immensely from any treatment that can reduce duration and increase efficacy, both of which the new treatment drugs have the potential to do.

Neither of those have been approved by the Pharmaceutical Benefits Advisory Committee as yet. One is before it at the moment and the other is to go before it later. But the people are very well aware of clinical trials. They are very well aware that these drugs are already on the market in America. They are sitting there thinking, 'Do I wait or do I go with treatment now?' Do they look for something that has a much bigger benefit to them in terms of the cure rate if they wait, or do they go with something that the rest of the developed nations are now considering lower-level treatment?

Senator FIERRAVANTI-WELLS: And hence, of course, your comment about the nervousness and concerns. That process with the PBAC has been ongoing for quite some time. I assume it is a pharmaceutical company that is undertaking that?

Ms Tyrrell: There are two pharmaceutical companies.

Senator FIERRAVANTI-WELLS: Who are they?

Ms Tyrrell: Janssen-Cilag is one and Merck is the other.

Senator FIERRAVANTI-WELLS: You make a comment here that:

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.

From your perspective, has that been clear from the comments you have received? You have obviously received quite a lot of complaints and commentary.

Ms Tyrrell: We are aware of many people who do not know what to expect, what to do and how to plan their lives at the moment. We are also aware, from talking to the pharmaceutical companies as well, that they are uncertain of what will happen in the coming months.

Senator FIERRAVANTI-WELLS: You mention here, at page 5 of your submission, the issue about cabinet and the time or the expertise in relation to these that are less than $10 million. You say:

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.

Do I read into your comment that there is a certain degree of double standards and a degree of hypocrisy by the government?

Ms Tyrrell: There are several aspects in relation to that. The current government is certainly pushing consumer involvement and transparency. Both those aspects seem to have been missing from this change.

Senator FIERRAVANTI-WELLS: When did you first become aware of the decision?

Ms Tyrrell: When the PBS drugs were not listed at the time of the announcement.

Senator FIERRAVANTI-WELLS: Do you have quite a good engagement with government? Are you the peak body that engages with government in relation to hepatitis issues?

Ms Tyrrell: We are. Hepatitis Australia has membership of the intergovernmental committee on blood-borne viruses and STIs, and our vice-president is also a member of the ministerial advisory committee. The first we knew of this was when the decision was actually made.

Senator FIERRAVANTI-WELLS: And, in relation to these two new potential medicines, have you done some assessment as to the potential cost savings?

Ms Tyrrell: We have not. We do not consider that to be our role. That really is a matter for the Pharmaceutical Benefits Advisory Committee. We are happy to take the outcome of the Pharmaceutical Benefits Advisory Committee as the umpire's decision, and we understand that both the costs and the benefits are considered as part of that process. If either of those drugs were not passed by the PBAC, I think our members would accept the fact that the clinical efficacy in clinical trials is absolutely clear-cut, so there obviously needs to be a review of financial implications if that is the case. And we support that process. As I said, as consumers we have an interest in having a sustainable PBS, but we put our confidence in PBAC as the expert committee determining that.

Senator DI NATALE: Thank you for your submission, Ms Tyrrell. I am interested in the question around some people choosing to delay treatment while waiting for a potentially more effective treatment option to become available. Just out of interest, can you tell me what that is? I would like to keep my eye out for that.

Ms Tyrrell: The current treatment?

Senator DI NATALE: No, I know what the current treatment as. But what is on the horizon?

Ms Tyrrell: There are new small molecules coming through; one is called boceprevir and the other is called telaprevir. If you add either of those new molecules to the current treatment—which is pegylated interferon and ribavirin—there is significantly increased efficacy for treatment of the hardest to treat genotype, which is genotype 1.

Senator DI NATALE: I just want to get this on the record. What are the consequences of delaying treatment for hepatitis C? What is the natural history of the disease?

Ms Tyrrell: Without treatment, it depends on how long you have had the disease. Without treatment, the disease can lead to increasing liver fibrosis, cirrhosis, liver cancer, the need for a transplant, liver failure and death.

Senator DI NATALE: The deferral of any potential advance in this area would therefore be significant.

Ms Tyrrell: It absolutely would.

Senator DI NATALE: I am also interested in the prevention of hepatitis C. Hepatitis C is transmitted largely through the sharing of dirty needles.

Ms Tyrrell: That is correct. Eighty per cent of cases in Australia, and 90 per cent of new infections, are associated with the sharing of injecting drug use equipment.

Senator DI NATALE: Do you know how many people are infected with hepatitis C virus at the moment?

Ms Tyrrell: In terms of chronic infection, 217,000 people are infected. We have a fairly well-regarded estimation process that is conducted periodically with one of the national research centres. The last time that was conducted, it was estimated that there were 9,700 new incident cases of hepatitis C each year. In terms of notifications, though—it is a notifiable disease—notifications are higher because most people are not actually diagnosed until quite some time after the infection. At the time of infection, there are generally no health consequences whatsoever, or they go unnoticed. So people often do not know they have been infected until many years after the event.

Senator DI NATALE: This is an illness with a significant burden of disease—at one estimate, 217,000—which is caused by the sharing of injecting equipment. We know that a number of different substances are injected, but one that has become a serious problem is oxycodone. One of the preparations whose listing was deferred is the combination of oxycodone and naloxone—with potential for reduced injecting behaviour as a consequence. Do you think that might be of value in preventing hepatitis C?

Ms Tyrrell: The drug that is injected is irrelevant. Transmission is due to the fact that blood is on the actual injecting equipment. If contaminated blood is on the injecting equipment and it is transferred to the next person, then you will most likely get hepatitis C transmission. The actual drug injected is irrelevant.

Senator DI NATALE: The reason I mention that, though, is that one of the advantages of that combination is that there is less likely to be the potential for abuse because of the naloxone that is contained within the drug. My comment relates to the fact that here we have one of the six deferrals, which has the potential to reduce injecting behaviour—

Ms Tyrrell: I would not agree that it has the potential to reduce injecting behaviour.

Senator DI NATALE: You disagree with the PBAC and the published evidence?

Ms Tyrrell: My view is that if people are going to inject drugs, they are going to find drugs to inject. If that is not available, something else will be.

Senator DI NATALE: I am not sure that the evidence supports that contention, but clearly we have a significant burden of disease. My question relates specifically to the prevention of hepatitis C, and I think that we have one drug that potentially could reduce injecting behaviour and it may be of interest to your constituents that there is a drug there that has some potential benefits in not just treatment but prevention as well.

CHAIR: Are there any further questions? Senator Fierravanti-Wells.

Senator FIERRAVANTI-WELLS: Ms Tyrrell, you heard the evidence given previously by Professor Sanson about the PBAC meeting in March?

Ms Tyrrell: No, I have not heard that evidence.

Senator FIERRAVANTI-WELLS: Okay. Do you or your organisation have any connection with members of the PBAC committee?

Ms Tyrrell: No, we do not.

Senator FIERRAVANTI-WELLS: Okay. Thank you.

CHAIR: Thank you, Ms Tyrrell, for your submission and for appearing today. That concludes the committee's hearings in the inquiry into the government's administration of the Pharmaceutical Benefits Scheme. I thank Hansard and the secretariat. Committee members will be in discussion over the coming weeks regarding a report.

Committee adjourned at 15:41