COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

COMMUNITY AFFAIRS REFERENCES COMMITTEE

Reference: Consumer access to pharmaceutical benefits

FRIDAY, 7 MAY 2010

CANBERRA

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SENATE COMMUNITY AFFAIRS

REFERENCES COMMITTEE

Friday, 7 May 2010

Members: Senator Siewert *(Chair)*, Senator Moore *(Deputy Chair)*, Senators Adams, Boyce, Carol Brown and Coonan

Participating members: Senators Abetz, Back, Barnett, Bernardi, Bilyk, Birmingham, Mark Bishop, Boswell, Brandis, Bob Brown, Bushby, Cameron, Cash, Colbeck, Jacinta Collins, Cormann, Crossin, Eggleston, Farrell, Feeney, Ferguson, Fielding, Fierravanti-Wells, Fifield, Fisher, Forshaw, Furner, Hanson-Young, Heffernan, Humphries, Hurley, Hutchins, Johnston, Joyce, Kroger, Ludlam, Lundy, Ian Macdonald, McEwen, McGauran, McLucas, Marshall, Mason, Milne, Minchin, Nash, O'Brien, Parry, Payne, Polley, Pratt, Ronaldson, Ryan, Scullion, Sterle, Troeth, Trood, Williams, Wortley and Xenophon

Senators in attendance: Senators Fierravanti-Wells, Moore, Ryan and Siewert

Terms of reference for the inquiry:

To inquire into and report on:

Consumer access to pharmaceutical benefits and the creation of new therapeutic groups through the Pharmaceutical Benefits Scheme (PBS), including:

a. the impact of new therapeutic groups on consumer access to existing PBS drugs, vaccines and future drugs, particularly high cost drugs;

b. the criteria and clinical evidence used to qualify drugs as interchangeable at a patient level;

c. the effect of new therapeutic groups on the number and size of patient contributions;

d. consultation undertaken in the development of new therapeutic groups;

e. the impact of new therapeutic groups on the classification of medicines in F1 and F2 formularies;

f. the delay to price reductions associated with the price disclosure provisions due to take effect on 1 August 2009 and the reasons for the delay;

g. the process and timing of consideration by Cabinet of high cost drugs and vaccines; and

h. any other related matters.

WITNESSES

Committee met at 8.31 am

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

DELAAT, Mr Will, Chairman, Medicines Australia

SHAW, Dr Brendan, Chief Executive, Medicines Australia

CHAIR (Senator Siewert)—Welcome. The committee is commencing its inquiry into consumer access to pharmaceutical benefits. I understand you have been given information on parliamentary privilege and the protection of witnesses and evidence. We have read your submission. I invite you to make an opening statement.

Mr Delaat—Thank you for the opportunity to appear before the committee today on behalf of Australia's innovative medicines industry to discuss matters that are extremely important to ensuring timely and universal access to medicines through the Pharmaceutical Benefits Scheme. Medicines Australia represents the collective interests of the innovative medicines industry in Australia. Our membership comprises some 50 companies. Medicines Australia members manufacture about 80 per cent of all PBS prescription medicines. Our membership is committed to ensuring the long-term financial sustainability of the PBS in Australia. This has been shown though our commitment to recent systematic reforms of the PBS which are estimated to save government $5.8 billion over 10 years.

I do not intend to repeat the arguments presented in the Medicines Australia submission. However, I want to use this opening statement to draw the committee's attention to the importance to Australian consumers of affordable and timely access to new medicines. Medicines Australia believes that, for Australia to enjoy economic prosperity, one of the key ingredients is a healthy workforce. This is best achieved through a universal health system that provides timely and universal access to medicines. The PBS undoubtedly provides for a significant economic benefit to Australia through significant health benefits achieved. However, the government has a number of policy levers that permit ad hoc interventions into the highly efficient pharmaceutical market. Medicines Australia believes that the integrity of the PBS may be undermined because of several critical policy measures which pose a serious risk to patient access to pharmaceutical benefits.

The first policy lever I would like to discuss is the therapeutic group premium policy. I would like to begin by defining exactly what a therapeutic group is and, more importantly, what a therapeutic group is not. A therapeutic group is defined by the government as a group of two or more different medicines that deliver the same health outcome at the same price. However, for medicines to be included in a therapeutic group, they must be interchangeable with each other at an individual patient basis. As I will discuss shortly, this concept of interchangeability has not been defined.

Finally, a therapeutic group can mean an increased patient cost where the therapeutic group premium is applied on top of the normal patient co-payments. A therapeutic group is not comprised of medicines which are bioequivalents with each other or copy medicines. Such copy medicines are often called generics. Unlike these, the different medicines within a therapeutic group are not able to be substituted for other medicines in the group by pharmacists. A

therapeutic group includes two or more different medicines of which there may be many brands. Essentially, the different brands of the same medicines are substitutable and therefore can be substituted by a pharmacist at the pharmacy counter. But, where different medicines are deemed interchangeable, the doctor has to prescribe a different medicine; the pharmacist cannot do that.

We believe that the four therapeutic groups announced last year—the high-potency statin group, oral bisphosphonates for the treatment of osteoporosis, oral bisphosphonates for the treatment of Paget's disease and a selected antidepressant group—were implemented purely as a PBS savings measure without transparency or due process. The government neither consulted with affected companies or other relevant stakeholders prior to the announcement nor published a summary of their decisions. In fact, PBAC advice to government on the creation of therapeutic groups and assigning medicines to these groups does not appear in the public PBAC document summaries.

There has never been clear guidance given to companies as to the criteria and evidence required to determine whether medicines in a therapeutic group are interchangeable on an individual patient basis. When you get down to it, the concept of interchangeability is ill defined, and this has a variety of implications. The evidence required for determining interchangeability and therefore eligibility for this policy matter is different from that routinely provided within an application for reimbursement. Typically, such evidence is not available from companies' submissions to the PBAC. So where is the evidence in support of these decisions coming from?

On a number of occasions Medicines Australia has approached the Department of Health and Ageing and the PBAC to seek answers to the questions: what constitutes interchangeability on an individual patient basis and what evidence is used to determine interchangeability on an individual patient basis? No answers have been provided. This lack of clarity creates uncertainty and risk for consumers and affected companies. The risk for consumers is whether these medicines truly are interchangeable on an individual patient basis, whereby patients are able to switch from one medicine to another medicine in that group without detriment to their health. Because the establishment of therapeutic groups may introduce a financial consideration to a doctor's prescribing—because the physician may prescribe one medicine over another to avoid an additional patient cost—it is critical that conclusions of interchangeability are based on robust evidence.

The risk for affected companies is directly related to business certainty and is created by unpredictable short-term cost savings measures such as therapeutic groups. Companies need a stable PBS policy environment in order to provide timely access to new medicines. The more uncertainty a company encounters in the PBS policy environment, the less likely the company will invest in listing new medicines on the PBS. At best, this uncertainty will delay access to new medicines. At worst, some medicines may not be made available at all. Business certainty is critical to the investment environment. Concerns around reduced access to medicines—those currently on the PBS as well as innovative medicines not yet listed—were raised when the previous therapeutic groups were introduced in 1998.

Another key issue that goes directly to timely access to medicines relates to the current requirement for cabinet approval for certain medicines. Medicines Australia believes that the requirement for cabinet approval of new medicines that cost more than $10 million per annum delays timely access to new PBS medicines. The requirement for cabinet approval was

introduced in 2001 and implemented to reduce financial risk to the Australian government. However, the requirement for cabinet approval can delay the listing of these medicines for 12 months or more. While patients wait for the cabinet to review a positive recommendation that has already been made by the PBAC, there is no subsidised consumer access to that new medicine.

As a direct result of this policy, patients may experience deterioration in their condition before gaining access to their medicine and even premature death. New medicines undergo a rigorous cost-effectiveness assessment by the PBAC. Only if the PBAC is satisfied that a new medicine will provide value for money will the medicine be listed on the PBS. In addition, the government has implemented a number of measures aimed at further reducing the financial risk. Measures such as risk-share agreements spread the financial risk between the government and the affected company. We believe it is not good administrative practice for cabinet to be required to approve medicines for listing on the PBS, and we certainly believe that the $10 million threshold introduced at the turn of the century should be increased as recommended by the government's own Productivity Commission. It makes no sense that patients are being made to wait for sometimes life-saving treatments for a bureaucratic process whose rationale is unclear at best when those medicines have already been rigorously evaluated. At the very least, there are some medicines that simply should not get trapped in the cabinet process, and we are asking for the threshold to be updated to take account of that.

In concluding, Medicines Australia agrees with government that a financially sustainable PBS is essential for sustaining universal access to medicines. However, Medicines Australia believes there are a number of policy levers that risk timely consumer access to medicines and urges the government to, firstly, abolish the therapeutic group policy and legislative provisions relating to it, because it places consumer health at risk and creates business uncertainty; ensure the term interchangeability on a patient basis is clearly defined and guidance provided on the evidence required to establish such a link between these medicines; and, finally, review the $10 million cabinet threshold and process to avoid delays in consumer access to new, innovative medicines.

CHAIR—Thank you very much.

Senator FIERRAVANTI-WELLS—I start on the undermining of the recent PBS reforms. That is very clear from your submission. Is this going to derail those PBS reforms? Is it that bad?

Mr Delaat—Firstly, let me just say that Medicines Australia worked very closely with the government to develop those PBS reforms a couple of years ago and is involved with the implementation of those reforms. What this does is undermine those reforms, because the way the PBS was set up it created two separate formularies: F1 formulary, which is a formulary for single sourced, normally patented medicines; and an F2 formulary for multisourced, normally off-patent medicines—two different formularies. The idea with that was that there would be certainty in the F1 formulary for so-called patented medicines going forward for companies when they bring products onto the market in Australia, whereas in the F2 formulary there would be market competition based on the supply from many, many suppliers of those generic medicines. So the concept of paying for outcomes was destroyed in some way. In F1 the government is certainly paying for outcomes, but in the F2, multisourced formulary the government is really paying the lowest market price based on the competition in that area. They are not paying for outcomes. To reduce cholesterol by a certain degree will cost differently

depending on the reimbursed price in that medicine. Essentially, to answer your question, what this does is undermine. By linking products in F1 and F2, you totally undermine the principles of PBS reform.

Senator FIERRAVANTI-WELLS—To pick up the point that you made about business uncertainty, what is very clear in your submission and the submissions of others is that this is going to create such a high degree of uncertainty in future availability, particularly with new pharmaceutical launches in the future.

Mr Delaat—That is right. If companies do not know upfront—if the minister has the power to introduce therapeutic groups on a whim, so to speak, or at least to introduce them without any notice—it makes it very difficult from the perspective of predictability for the company bringing those medicines to the market. They want to know that they will not be hit with linkage to an F2 product, if they are bringing the product into F1, and therefore have that product brought down in price by 12½ per cent measures or other measures which affect those products in the multisourced category.

Senator FIERRAVANTI-WELLS—Even though the PBS reforms were negotiated with the previous government, the opposition at the time and the now minister made favourable comments about the reforms. From your perspective, you have gone into those reforms in good faith and now all of a sudden you have got the minister intervening in the market in a very determined manner. My question to you is: ultimately, this is really about saving money rather than patient outcomes, isn't it?

Mr Delaat—It is.

Senator FIERRAVANTI-WELLS—That is really what it is about when you boil it down.

Mr Delaat—It is. This particular measure really provides minor savings compared to the huge savings that were going to accrue from PBS reform and will accrue from PBS reform. PBS reform was originally estimated to save the government $3 billion over 10 years. It is now been estimated to be almost double that, with $5.86 billion savings over the 10-year period. So this measure is very small in comparison to what would happen with the efficient implementation of PBS reforms. They are going to deliver the big savings.

Senator MOORE—When you say 'this measure', you mean the therapeutic—

Mr Delaat—The therapeutic group premium measure, yes.

Senator FIERRAVANTI-WELLS—In effect, for a cash-strapped government, it is a convenient way to find money. That is really what it boils down to, Mr Delaat.

Mr Delaat—That would be our view of why this measure has been introduced.

Senator FIERRAVANTI-WELLS—That is right. So it is about picking and choosing drugs that are going to deliver a big bang for your buck and get good savings, and that is some money, despite what protestations or assurances may have been given in the past about supporting the PBS. That is what it comes down to politically, doesn't it?

Mr Delaat—Certainly, that would be view.

Senator FIERRAVANTI-WELLS—Can I take you to the definition of interchangeability, which is a topic in your submission. In both your submission and your opening statement you mentioned that you have asked the department about the issue of interchangeability. What specific information or documents have you sought from the government in relation to a definition of 'interchangeability'?

Mr Delaat—I might ask Mr Bruce to answer that one.

Mr Bruce—On a number of occasions we have spoken to officials from the department and even the PBAC. The term 'interchangeability' on a patient basis appears in the National Health Act, so in our minds it is a term in law. It is an issue that causes substantial uncertainty for companies, so we thought it reasonable that they provide some sort of advice as to what it in fact means and what the evidential requirements for that are. It was never a question of disputing the legislation at this point in time; it was simply: can you provide our companies with some guidance?

It is one area where we have found our relationship with the department and even with the PBAC a little bit strained. They have quite obviously been reluctant to talk about this at all, which I guess brings it back to this idea that we suspect it is principally a pricing issue masquerading as a clinical issue, because at the heart of it, if it was a clinical issue, I cannot see why they would be so reluctant to sit down with us and say: 'This is what we think this means. These are the sorts of things we're looking for. These are the sorts of characteristics of products that we think we would comfortably group together, and this is the evidential basis of those decisions.' As I said, we just have not had any success whatsoever with that. We have asked them on a number of occasions, formally and informally, and we have basically been stonewalled on it.

Senator FIERRAVANTI-WELLS—Mr Bruce, I have two questions on the legalities. I would appreciate your assistance in relation to this. In the National Health Act, section 84AG says, about the minister making a determination in relation to therapeutic groups:

… the Minister must obtain the advice in writing of the Pharmaceutical Benefits Advisory Committee in relation to the proposed determination.

But, interestingly enough, in making that determination, it says:

… the Minister may have regard to advice … by the Pharmaceutical Benefits Advisory Committee to the effect that a drug or medicinal preparation should, or should not, be treated as interchangeable on an individual patient basis with another drug or medicinal preparation.

It raises the question: who initiates the determination? Is it the minister or the PBAC?

Mr Bruce—It is difficult to tell. The groups have been formed around the MYEFO and the budget consideration. So, even more than usual, I guess, it has been more difficult to understand—

Senator FIERRAVANTI-WELLS—That lends credence to it being a budget issue rather than a health issue.

Dr Shaw—I think that transparency around the process is not there, so we actually do not know the process of how those groups are formed or how they are initiated. The first we find out about those particular groups is when they are announced either in the budget or in the MYEFO. There is no consultation prior to that.

Mr Bruce—I think it is also interesting that there is another section of the act under which the PBAC is obligated to provide to the minister, at a point of listing a drug, whether that drug is to be considered interchangeable on a patient basis. For all other decisions, the decisions of the PBAC appear in the public summary documents a couple of months after those decisions, as a point of transparency. There is, for some unknown reason, a reluctance to include this part of the advice to the minister in those decisions.

CHAIR—Can I seek clarification. When the initial decision is made, there is a decision made about interchangeability—is that what you have just said?

Mr Bruce—When there are applications for a new listing to the PBAC, the legislation, as far as we understand it, obligates the PBAC to advise the minister if they believe that it is interchangeable on a patient basis.

CHAIR—And that is the bit that is not in the public notification?

Mr Bruce—There is nothing about that in the public summary documents. I get to see documents that companies do not get to see—committee-in-confidence documents that I cannot pass on—so I know that somewhere in that advice it has been provided. But I cannot for the life of me see what is so special about this advice that it cannot also be made transparent to the company at that point of decision. It is curious, at best.

Senator FIERRAVANTI-WELLS—Following on from Senator Siewert, the problem is that there is no definition in the legislation or the regulations relating to the National Health Act that defines interchangeable on an individual patient basis with another drug or medicinal preparation.

Mr Bruce—I would go even further than that. It is actually downright confusing, to the extent that the word 'interchangeable' appears in the National Health Act on a number of occasions meaning different things depending on the context, so to be able to infer the definition from one to the other is confusing at best.

Senator FIERRAVANTI-WELLS—What do you see as the appropriate definition of 'interchangeable'? It is obviously a problem legislatively. How would you fix it?

Mr Delaat—I do not know that there is a very simple, pat answer to that question that we could provide here, other than to say—

Senator FIERRAVANTI-WELLS—Please take it on notice, Mr Delaat. It is clear that the definitional issue about interchangeability is going to exercise us today. If Medicines Australia

has a view as to what the appropriate definition should be or where you believe there should be reform of these areas, then certainly I would appreciate receiving that.

Mr Bruce—We have done some work on this and I think we would be happy to provide the committee with some of that work. As a principle, if a patient has been taking a certain drug for a period of time and they have stabilised on that drug and are getting good outcomes on that drug, there has to be confidence that that patient can be switched to another medicine without detriment to that patient's health. There are some technical evidentiary requirements that would need to be satisfied to have that confidence, and I think we have done some work on that. We did not bring it today, unfortunately, but I think we will be glad to table it at a later date.

Senator FIERRAVANTI-WELLS—Given the time restrictions, I would just like to ask you how you would see improvements being made to increase transparency. You make comments in your submission in relation to that. You may prefer to answer it now or to take it on notice and provide further evidence to this committee.

Dr Shaw—We are happy to provide evidence on notice. A general comment would be that at the moment the groups are announced essentially in the budget papers with no consultation with the companies or notification. The first the companies or the industry find out about it is on budget night or in the MYEFO documents. Some sort of process at least where the companies are involved in the discussion prior to that would be a step forward. We will certainly provide some more comments to the committee.

Mr Bruce—The thing it needs to get back to is that we believe this undermines the very principles upon which PBS reform was founded—that is, there are two different price-setting mechanisms: one is F1, which is what the evidence suggests is value for money, and the other is F2, which is a commodity market where competition drives prices lower and the government gets efficiencies and savings out of that. We do not believe that this policy per se should exist. It undermines the agreement that we have come to.

Senator MOORE—I want to clarify a couple of points. Your concern in this process is the four groups that were introduced last year; you have no concerns with the previous groups—is that right?

Mr Delaat—We have concern with therapeutic group premium policy overall. It originated over 10 years ago. We would like to see it removed from legislation. We think it is bad policy. For all the reasons that we have elaborated on today and in our submission we believe—in the context of the PBS reform; prior to PBS reform a couple of years ago it might have had a place—that certainly today, with an F1 and an F2 formulary, different formularies with different objectives, it really does not have a place and therefore is bad policy in today's environment.

Senator MOORE—Did the discussion of interchangeability refer to the original groups as well, or has that only become important since last year?

Mr Delaat—The issue has been important for 10 years. For the PBAC, as I am sure Professor Lloyd Sansom will say later on today, interchangeability is based on whether a product is submitted to the PBAC on a cost minimisation basis as opposed to a cost-effectiveness basis—in other words, it is not inferior to the product with which it is being compared. But that is really

saying the drug is not inferior on a population basis, not when you get down to individual patients taking individual medicines and then being encouraged to change because they might have a premium put on top of them. There is a difference between a population basis submission to the PBAC and interchangeability on a patient basis.

Senator MOORE—I still want to clarify. We have been struggling with this as a committee over many years. You know; you have come before our committee a number of times. With regard to the issue around interchangeability: was that only introduced last year?

Mr Delaat—No. Therapeutic group premium policy assumes interchangeability. If you go back to 1998, with the first groups, it would assume that those medicines could be interchanged.

Senator MOORE—So the concept of interchangeability has been around since the beginning of the therapeutic groups?

Mr Delaat—Yes.

Senator MOORE—Mr Bruce has been talking about the inability to get a definition. Has there been an inability to get a definition for over 10 years?

Dr Shaw—I think it is the first time in a piece of legislation, as far as I am aware.

Senator MOORE—I understand, but this is a longstanding issue. It needs to be considered, absolutely, but the focus on the last 12 months interests me as well. We need to get to the bottom of it. The department's submission to us refers to a discussion we had in community affairs with the then assistant secretary of the department and includes a paragraph on interchangeability, which seems to be the basis on which publicly people have concerns. Your view is that the wording does not meet the requirement of interchangeability for your industry; is that the core point?

Mr Delaat—Yes.

Senator MOORE—Okay. But this has been longstanding—

Mr Delaat—Yes.

Senator MOORE—and in fact therapeutic groups as a whole policy, not specifically what happened last year, is part of an ongoing debate?

Mr Delaat—Yes.

Senator MOORE—I want to clarify something that is really important in terms of the ongoing discussion with the department. Your submission and evidence indicate that you have been trying to get some response. I am interested to know exactly: do they not respond? The way your submission reads, you ask them; you want a definition. Would the response be, 'We're not giving you one'? Would it be, 'We're moving on to another paragraph and ignoring it'? From your perspective, what is the response?

Dr Shaw—The response is fairly circular, I think, because it is: 'What's interchangeability? Well, it's something that's interchangeable at a patient level.'

Senator MOORE—Sure.

Dr Shaw—Then we ask them, 'What does that mean?'

Senator MOORE—'So what is world peace?'—that kind of thing?

Dr Shaw—Yes.

Senator MOORE—So the word is used without definition?

Dr Shaw—That is right. Eventually the discussion becomes: 'Well, it's when the PBAC recommends that something is interchangeable at the patient level.' We say, 'Okay, what does that mean?' They say, 'When the PBAC says it is.' I think it is probably fair to say that it has been a circular argument. There is no list of criteria, no definitions or anything like that.

Mr Bruce—The closest we got to any specific advice was that cost minimisation—that is, a product is cost minimised to another—is a necessary but insufficient condition. On that basis—

Senator MOORE—I think I would need to see that written down.

Dr Shaw—There are lots of drugs that can be cost minimised together that you would not call interchangeable—drugs for mental illness and depression, that sort of thing—so it does not provide the clarity that is needed.

Senator MOORE—We will certainly ask other witnesses about this. The concept is that they are a group of drugs that serve a similar purpose—and I will not get into debating a definition. There is always the ability, and always has been the ability, for the practitioner to determine which medication someone uses. This legislation does not change that at all, so the concept that this is overriding the role of the practitioner in discussion with the client is not affected. What you are saying is there could be other things that colour that.

Mr Delaat—It brings in a financial consideration for the doctor which would not have been there otherwise. In other words, now the doctor has to consider whether the patient, who may only be paying $5.30 as a pensioner for a prescription, may have to pay an extra $3 or $4 in additional premium, which would take the cost up to $8 or $9 when they are taking four or five other medicines as well. So there is a financial consideration: 'Is this the right medicine of this patient? It may be, but I don't really want to give that financial burden to the patient because they can't afford it.'

Senator MOORE—As opposed to the ongoing discussion about whether it is on the PBS or not, which has always been part of the process, and also the discussion we have had in this group about whether a generic drug will serve us. We have had a long discussion about that, which has already been part of the process for many years. You are saying this is an added impost.

Mr Delaat—It is.

Senator RYAN—I have a couple of brief questions because this is an incredibly complex area. In terms of therapeutic groups, the submission is based on population data, the effect of medicines across populations. I just want to make clear that they are not actually the same molecules that are being grouped together, they are actually different medicines—different forms of statin and different forms of antidepressants.

Dr Shaw—Correct.

Senator RYAN—It is fair to say that even though they may be equivalent of a population level any one of those statins or an antidepressants may work in someone better than it works in someone else, so patients may need to change.

Dr Shaw—Correct.

Mr Delaat—And particularly in mental health, because antidepressants and other medicines used in mental health are so idiosyncratic in the way that patients respond to them. As the Epilepsy Foundation's submission said, they have case studies where even when a person goes to a generic version of the same medicine they get out of control, let alone going from one medicine to a totally different medicine.

Senator RYAN—I want to explore that in relation to antidepressants and the therapeutic groups there. When you are treating people or trialling them on different medicines, there is a period of titrating doses are up and down in between changing medicines, isn't there?

Mr Delaat—Correct.

Senator RYAN—So the idea that some of these medicines might be interchangeable at a patient level for that class of medicines is basically ridiculous because you would be titrating people down on a dose of one before you could put them on another one, and that is assuming they could be stable on both.

Mr Delaat—That is correct. If you take the statins, where there are four or five different dose levels for cholesterol lowering and side-effect profiles, patients might get some unwanted effects at high doses so you titrate backwards. So there is always that titration period, and then to think that you can switch them easily to another product means you have got to go through the whole process again.

Senator RYAN—I think that is one of the more important points. There is often an assumption that the question of therapeutic groups can be mixed in with the debate about generic substitution.

I want to go to the issue of cabinet approval of medicines, which I know has been covered on numerous occasions. Your submission talks about what is effectively a 50 per cent increase in the delay of approval of medicines at cabinet, from 200 days to just under 300 days—a full year. Have you been given any explanation of why there has been a 50 per cent increase in two years in the approval of new medicines?

Dr Shaw—No, we have not. My understanding is that it is based on just an observation of the date when the PBAC makes a positive recommendation to the date that it is listed on the PBS, and that is just an analysis based on publicly available data. Our view is that the cabinet process generally adds six to 12 months to listing time. Given that Australians are already waiting three years for a medicine to appear on the PBS, that process needs to be looked at. All we are saying in the submission today is that the threshold where that cabinet approval needs to kick in needs to be readjusted, given that the level was set back in the turn of the century.

Senator FIERRAVANTI-WELLS—In fact, you are correct. In answers to questions at estimates the government has admitted that it has doubled. It has gone from about 5.5 months to 10 months, so you are absolutely correct. Before the last federal election, Medicines Australia, I think, was given some commitment by then shadow and now Minister Roxon in relation to the threshold. Did you get that in writing?

Dr Shaw—We can investigate that. We are happy to take that on notice.

Senator FIERRAVANTI-WELLS—In other words, she gave a commitment that she would look at the threshold.

Dr Shaw—As I understand it, yes. We can have a look at that.

Senator FIERRAVANTI-WELLS—What has happened in relation to that?

Dr Shaw—We have subsequently approached the government in discussions about increasing the cabinet threshold, and I think the response has been 'it's a cabinet matter'. As I say, our argument has always been that the threshold should be increased. The $10 million threshold was set back in 2000 or 2001, and even just by indexing it to inflation it would be up to $20 million. We think it needs to be increased.

Senator FIERRAVANTI-WELLS—Dr Shaw, can you take that on notice and see if you can produce that letter. It might turn out to be a bit like the letter that the Prime Minister wrote to Dr Armitage about private health insurance: it may not even be worth the paper it is written on. But if you could give that to the committee that would be very helpful. Thank you, Doctor.

CHAIR—We will take that last issue as a comment.

Senator FIERRAVANTI-WELLS—I am entitled to comment.

CHAIR—Unfortunately, we are out of time. Thank you very much. We have given you quite a bit of homework, I think!

Mr Delaat—Before we go, if I could just make one point. I notice that one of the later speakers before the committee is Professor Lloyd Sansom, Chairman of the PBAC, and he has not provided a submission to this committee. We would respectfully request that there be some opportunity for us to respond to what he has to say, because we have not seen what he is going to say. He has not put in a submission and we would like the opportunity to respond.

Senator FIERRAVANTI-WELLS—Yes.

CHAIR—There is always an opportunity for people to put in supplementary submissions, and of course we accept supplementary submissions. Just bear in mind the time frame.

Senator FIERRAVANTI-WELLS—Chair, on that point, we may need to recall some witnesses based on what evidence the department presents. That option should perhaps be considered at this point.

CHAIR—That will be a decision for the committee. But, yes, it is our practice to accept supplementary submissions.

Senator MOORE—As you know, Mr Delaat!

Mr Delaat—Yes.

CHAIR—Thank you very much. We do have a fairly tight time frame on this inquiry; so, if you could get your homework done—

Mr Delaat—Certainly.

CHAIR—so that it facilitates our review of that information, that would be appreciated. Thank you.

Mr Delaat—Thank you very much indeed for hearing us.

[9.07 am]

CONDOLEON, Dr Alex, Medical Director, Sanofi-aventis

FISHER, Dr Simon, Senior Director, Medical and Regulatory Affairs, AstraZeneca Pty Ltd

JAMES, Mr Timothy Charles, Manager, Corporate and Government Affairs, Janssen-Cilag Australia

LINDSAY, Mr Paul, Public Affairs Director, Sanofi-aventis

MILES, Mr David, Senior Manager, Government Affairs, Pfizer Australia Pty Ltd

SCHNEEMAN, Mr Kieran, Government Affairs Director, AstraZeneca Pty Ltd

STEWART, Dr Peter, Primary Care Medical Head, Australia and New Zealand, Pfizer Australia Pty Ltd

CHAIR—I welcome representatives from Pfizer Australia, AstraZeneca, Sanofi-aventis and Janssen-Cilag. Now, I understand you have all been given information on parliamentary privilege and the protection of witnesses and evidence. We have your submissions, which we have read. We have a tight time frame. I do not know if a representative of each company wishes to make a brief opening statement before we get into questions, but I would urge you to keep those statements short, because we have lots of questions. Who wants to start? Mr James.

Mr James—Yes, that is our intention. We will move from left to right down the table.

Senator MOORE—Always a good idea, Mr James!

Mr James—Thank you, Senator! My statement will be followed by statements from industry colleagues—from AstraZeneca, Sanofi-aventis and then Pfizer.

Mr James—Senators, thank you for this opportunity. Johnson and Johnson is the most broadly based healthcare company globally and locally. For nearly 70 years our credo has guided J&J and likewise Janssen-Cilag, our local pharmaceutical company. Our first responsibility is to patients, to mothers, fathers and others who use our products. Over one million Australians use our products every day. All of us are patients at some point in time. At Janssen we believe that by understanding our patients, their needs, challenges and differences, we can best help them. We have come to know that each and every patient is unique. We know our medicines and the impact they have on patients better than anyone else can possibly know these treatments and their effects.

Janssen has not to date been impacted by the therapeutic group policy but we know it is bad for patients, and that is why we are here. The fundamental problem with therapeutic groups is their presumption that different medicines bring about the same outcomes in patients. They do not. We are dealing with separate molecules, different chemical formulations, individually

developed and trialled by separate companies in separate patient populations. Yet this policy presumes to know better than what the medical and scientific community has accepted for decades—namely, different people respond differently to different medicines. There are different outcomes, different risks, different benefits and, therefore, different values attached to those medicines and outcomes.

Janssen has a particularly strong heritage and presence in mental health medicines. There are greater challenges around medicine access, utilisation and treatment success in this area of health. This policy would have particularly detrimental impacts among mental health patients in terms of confusion, concern, complication, additional medical consultation, treatment noncompliance and higher monetary cost. We note and strongly share in the concerns expressed by many other stakeholders, including the Mental Health Council of Australia, Epilepsy Australia and Carers Australia.

Therapeutic groups, in short, are an ill-conceived, blunt, cost focused and consultation-free policy measure that undermine Australia's strong track record in caring for people in our community. Please join with us in putting patients first and move to end this policy.

Mr Lindsay—Sanofi-aventis has a wide range of products treating major diseases such as cancer, cardiovascular disease, diabetes and osteoporosis. We also have vaccines and complementary medicines. We are here today because we believe therapeutic groups are bad policy and should be abolished. It is clear that the government sees therapeutic groups as a cost-saving measure, not a health measure. We assert that therapeutic groups are inappropriate and unnecessary as a PBS cost-saving measure.

The medicines industry has worked with the government on extensive reforms to establish a system to capture savings from medicines once they go off patent. To give you a feel of how extensive these savings have been, an independent report has shown that the industry has signed up to $8.5 billion in savings over 10 years, well beyond the $3 billion expected at the time when the agreement was reached. We are also concerned that therapeutic groups unravel the intent of PBS reform. The arbitrary way in which therapeutic groups can be created and the fact that they can affect medicines still on patent serves only to create uncertainty about stability of the Australian market when companies are thinking about bringing new medicines here.

Our particular interest today is the proposed therapeutic group for oral bisphosphonate medicines which are used to treat osteoporosis. Osteoporosis is a crippling disease that affects up to 2.3 million, mostly elderly, Australians. Our product affected by the oral bisphosphonate therapeutic group is Actonel and its range of forms and combinations. We are deeply concerned about the decision that our medicine is interchangeable with other oral bisphosphonates and we strongly refute any suggestion that there has been an adequate consultation process in determining the oral bisphosphonate therapeutic group.

While the PBAC made its decision in June 2009, we were not informed until November, when the savings measure was announced in the MYEFO, some six months later. At the time we were told that the determinations to form the therapeutic groups would be issued in December and that the therapeutic groups would commence in April 2010. We were invited to make comments by 24 November. That is potentially only one week before the determination was actually going to be made. This was not a consultation process.

Dr Condoleon—I would like to outline two main concerns that Sanofi-aventis has with the formation of a therapeutic group for oral bisphosphonates. Firstly, in the absence of a clear definition and criteria for determining interchangeability at an individual patient level, we question the advice that has been provided by the PBAC to government. Additionally, I would like to outline the patient impact that could result from the formation of this therapeutic group. Interchangeability means that all medicines in a therapeutic group are the same. Actonel and alternative oral bisphosphonates are different chemicals. They have different biochemical and pharmacological effects. Indeed, the binding affinity with which they link to bone, where they have their effect, is different. As such, large clinical studies have shown different time to onset of fracture protection benefit for patients.

I would like to point out that Actonel is reimbursed for a different set of osteoporotic patients than the alternative oral bisphosphonate is. Today a doctor can write a PBAC script for Actonel for a specific type of osteoporotic patient, for whom they cannot write a script for the alternative oral bisphosphonate. How can Actonel be considered to be interchangeable when there is no real alternative in that specific osteoporotic population?

I have with me the range of Actonel products. You can take Actonel once a day, you can take it once a week or you can take just one tablet per month. Actonel can be given with calcium or it can be given with calcium and vitamin D. Doctors and patients will determine what the best treatment is in order to achieve the best outcome in that individual. If you look at the alternative bisphosphonate range, it does not expand all these options that you see before you. So there is a tailoring of treatment to individual outcomes.

Indeed, our product information, which was approved by the TGA, gives a warning that this class of drug should not be used in patients who have a low level of calcium in their blood, so there are safety and efficacy reasons for which doctors make choices at an individual level. Interchangeability means that we are getting the same outcome from all of these products and all of the alternative oral bisphosphonate products, but we ask: how can that be? This is a primary reason why we question the advice that has been given to the government by the PBAC.

I note that a number of individual doctors and associations focused on osteoporosis have made submissions to this committee. Like Sanofi-aventis, it would appear that they were not consulted in the process of reaching this determination and, like Sanofi-aventis, they are raising concerns about the determination of interchangeability. They have identified differences in these products that lead to real-world differences for patients. Not all osteoporotic medications are the same and not all osteoporotic patients are the same.

If this therapeutic pricing policy is to continue, we say that there must be a clear definition of interchangeability, there must be a clear set of criteria against which interchangeability is determined and there must be a clear and transparent process which engages key and relevant stakeholders such that the best decisions are made for our community and for patients.

Dr Fisher—I am here representing AstraZeneca as the medical director, but I am also a general practitioner who has treated patients in the Australian clinical environment. My intention is to take you into the general practice clinic and demonstrate how this pricing policy affects clinical medicine by using an example drawn from the high-potency statin therapeutic group, consisting of atorvastatin and rosuvastatin, also known as Lipitor and Crestor. I will demonstrate

how this poorly designed therapeutic group policy adversely impacts patient safety by increasing the risk of adverse events through ill-advised drug switching.

Nearly two years are spent on TGA and subsequent PBAC review to allow initial registration and subsequent listing on the PBS. These processes involve rigorous review of an extensive set of data to demonstrate safety and clinical and cost effectiveness of an individual medicine. By comparison, the decision around the clinical interchangeability of the highly potent statins was made without consultation and, critically, with an unknown amount of data review. This is entirely inconsistent and undermines the TGA and other PBAC review processes. The consequences of the formation of the group are significant at the clinical coalface.

There are many elements as to why these two medicines are not interchangeable. I will talk to just one of them—that is, the dosing of an individual patient. I will demonstrate this to you by asking you to refer to the previously submitted pictorial, which I believe you have in front of you, showing the complexity of having to change from one member of the group to the other. The pictorial draws on the fact that the PBAC have defined that the clinically equivalent dose of Lipitor to Crestor is three to one. For example, a dose of 40 milligrams of Crestor is approximately equivalent to 120 milligrams of Lipitor, as in the red box at the bottom of the page.

Suppose I am sitting in my rooms with a 45-year-old female. She has high cholesterol that runs in her family, and she must be on a highly potent statin. She presents to me today for a check-up. She has been taking 40 milligrams of Crestor, and as a result of this policy I find myself in a situation where I need to switch her medicine. In doing so, given that the respected PBAC have defined a ratio of three to one between these medicines, I need to prescribe 120 milligrams of Lipitor to achieve clinical effectiveness. I have to do one of the following. First of all, as in scenario 1, I can write two prescriptions—one for Lipitor of 80 milligrams and one for Lipitor of 40 milligrams—to achieve 120 milligrams. I have to ask the patient to take one tablet from one box and one tablet from the other box every day. Second, I can write one prescription for Lipitor of 80 milligrams and ask the patient to cut the second tablet in half to achieve 80 plus 40, or 120. It is clear that in scenario 1 this will increase the cost to patients by attracting two dispensing fees at pharmacies for the two prescribed doses of Lipitor. It is also clear that in scenario 2 tablet splitting is required. Tablet splitting is discouraged, as absorption into the body is unpredictable and inaccurate dosing can result.

A week later, I am called by the local public hospital to tell me that the patient has been admitted after having an adverse reaction. The dose of Lipitor I prescribed was not a registered dose and had not been studied. The patient has toxic levels of Lipitor in her blood, for which she has required hospitalisation. I ask myself why the respected PBAC have been put in this position and have said that these two medicines are interchangeable at the patient level. Through a pricing policy, not driven by the need to allow safe access to medicine, the PBAC have been placed in an untenable situation of advising that two chemical entities are interchangeable while there is no data to suggest this. This scenario could play itself out numerous times in numerous practices across the country every day because of the formation of this therapeutic group.

No two chemical entities are the same. In the case of Lipitor and Crestor, the TGA approved product information documents relevant to the two medicines differ in a number of ways and demonstrate clear differences in many areas of clinical relevance. No two patients are the same.

All patients vary in their ability to absorb, metabolise and excrete medicines, leading to individual variability of the effects of medicines at the patient level. To make rational and safe decisions about interchangeability would require collection and extensive evaluation of data, comparing relative efficacy and safety of medications at both an individual and a population level. In the case of the highly potent statin group, these are different medicines presented in different dosage forms with different relative effects which have been stated as interchangeable at the patient level. They simply are not. They have different safety and effectiveness profiles at the patient level and, critically, they cannot be exchanged dose for dose. To do so could result in serious adverse consequences for patients through either over- or underdosing.

Through this policy, by stating interchangeability, we are asking doctors to substitute one of two different medicines for the other based not on sound data but on a pricing policy. To date, therapeutic groups have been formed based on consultation with medical companies who develop these medicines, and this has gone some way to minimising patient risk. This latest application of the therapeutic group policy undermines the current and otherwise rigorous review of access to medicines in Australia. It is not evidence based and it puts patient safety at risk. I will now hand over to David Miles from Pfizer.

Mr Miles—Thank you very much. I thank the committee for the opportunity to appear before it. The therapeutic groups policy has been around for some time, since 1998. This policy, let us be clear, is nothing more than a savings measure. It is not a health policy. There is not a single Australian who will have their health improved as a result of this policy. In fact, in many cases, as we have heard, the policy will place patients' health at risk. When a savings measure runs the risk of placing patient health at risk, it is just not worth it.

The PBS is a good system. Indeed, it is a great system which seeks to ensure the Australian public has access to safe and effective medicines at a reasonable price. It is a system that Pfizer has and always will strongly support. Ensuring the public's faith in the system is why a medicine cannot be listed on the PBS without a positive recommendation from the PBAC. You have to wonder why the minister is compelled to ask the PBAC's advice to form therapeutic groups but has no requirement to listen to it. If the PBAC were, in fact, to advise against forming a therapeutic group, the minister could form it anyway. The PBAC has been placed in a very difficult position given this is clearly a savings measure and is not about patients.

The hallmarks of the PBAC have always been evidence, scientific rigour, transparency, consultation and safety. That is why everyone, including the AMA and the Consumers Health Forum of Australia in their submissions, have demonstrated the faith they have in the PBAC's recommendations. Unfortunately, these hallmarks appear to have been abandoned when it comes to the therapeutic groups policy, and this is very concerning for the integrity of the PBS. These concerns are not confined to the medicines industry. I note Dr John Eisman of the Garvan Institute of Medical Research in his submission expressed similar concerns. This measure was introduced without any consultation whatsoever with industry or any other stakeholder. Pfizer was first notified of the high-potency statin group half an hour before the government announced it as a savings measure in the budget. Similarly, we were not provided with any notice prior to the announcement in November of the therapeutic group relating to two of Pfizer's medicines to treat major depression. This is perhaps even more perplexing as it should not have been protected by the usual confidentiality of budget processes. What is disturbing is that the recommendation to form the group for depression medications came from the PBAC meeting in

March 2009 and was kept secret for eight months. Surely this time could have been used to conduct meaningful consultation with affected companies and stakeholders. Given the extensive process involved for both companies and the government when seeking to list a medicine on the PBS, it remains a concern for Pfizer that there appears to be little or no process associated with the creation of a therapeutic group.

Pfizer's major submission to the PBAC in 2005 to differentiate two medicines on the PBS contained more than 30,000 pages of evidence involving trials of tens of thousands of patients. By contrast, the advice from the PBAC claiming our medicine was effectively no different from another medicine contained one paragraph. That is what we received. No supporting information was provided and repeated requests from Pfizer to see the evidence to back up the claim of interchangeability have, sadly, fallen on deaf ears. I will hand to Dr Stewart.

Dr Stewart—I would like to make a few general points about the interchangeability of medicines in the same patient and then focus on the two therapeutic groups for which Pfizer has a specific interest. Firstly, as has been highlighted previously, only medicines with the same chemical structure can be expected to behave in exactly the same way in the body. That is to say that they are bioequivalent and, hence, can be said to be interchangeable on an individual patient basis. Even slight differences in chemical structures can result in significant differences in efficacy and safety outcomes. At the risk of labouring the point and providing a useful, if simplistic, non-medical analogy, we could look at comparing soft drinks—for example, a cola and a diet cola. At first glance it might appear that they have a lot in common and may be interchangeable. Both are mainly water, they are gassy, they come in the same sized cans, they have the same colour and so on. But whilst they may be very similar they do have important differences too, such as sugar content and caffeine content. If the same person drank them over two separate six-week periods, the effects on the body vis-a-vis weight gain, tooth health and stimulation would be very different, so clearly they are not interchangeable.

Today we are not talking about soft drinks but about powerful medicines that have far more significant impacts on patient health. Importantly, the fact that different medicines may have similar overall effects within a population does not mean that they are interchangeable on an individual patient basis. Implying so by placing them in the same therapeutic group, especially with the imprimatur of such a well-respected body as the PBAC, has the potential to mislead clinicians and even our representative organisations and result in confusion. It is worthwhile noting that the process of evaluation of medicines in terms of cost effectiveness is not precise or sensitive enough to detect individual differences, as it relies on quantifying value for populations

Secondly, I would like to touch very briefly on the two therapeutic groups that affect Pfizer—the statins and the antidepressant groups. Dr Fisher has already noted that there are distinct differences between the two statins Crestor and Lipitor. I would like to add a few points which further highlight these differences. In Pfizer's experience, many clinicians do not fully understand the one to three dose relativities between the medicines and thus they use inappropriately low or high doses when switching between them. The product information documents which inform clinicians on how to use the medicines also highlight important differences. For example, dose adjustments are required for Crestor in Asian patients and those with poor kidney function, and specialist supervision is recommended when prescribing the maximum dose. None of these conditions apply to Lipitor. It is therefore simplistic, misleading

and potentially risky to suggest that two medicines can be routinely interchanged in the same patient, as placing them in a therapeutic group would imply.

In closing I would like to make a few quick points about the antidepressant group. Antidepressants act directly on the brain and modify brain chemistry. It goes without saying that they need to be administered with great care. Switching a stable patient from one antidepressant to another may lead to relapse of symptoms, sometimes with devastating effects and very little warning. Often the first sign that a medicine is not working is a deterioration in the patient's mental condition. Effexor and Pristiq are probably the most similar compounds in the therapeutic groups in question. Nevertheless, there are important differences between them, the main one being at Effexor is changed or metabolised in the liver but Pristiq is not. This has a number of important clinical consequences in terms of interactions with other medicines, predictability of clinical response and adjustment of dose in patients with poor liver function. Again, implying that these medicines are interchangeable on an individual patient basis is fraught with complications. Finally, even the head of the Mental Health Branch, Dr Harvey Whiteford, noted during Senate estimates in 1997 that switching patients between antidepressants could negatively impact their health. It is worth noting that, following this estimates hearing, the proposal for such a therapeutic group was abandoned. Thank you.

CHAIR—Thank you.

Senator FIERRAVANTI-WELLS—Dr Stewart, your comment about the confusion on one-to-three also baffled Dr Primrose, head of pharmaceuticals at the Department of Health and Ageing, at the estimates in February, so you are not alone. If that head in the department cannot get it right, it is understandable that the average person out in the street would have confusion about the one-to-three, so I think that point is very well made. Picking up on your last point, at the 1997 estimates when this matter was last raised, I think it was Dr Whiteford, who is still in the department, who made those comments in relation to antidepressant drugs. After due scrutiny of the Senate, as you correctly say, it was abandoned, but it was not the same consideration. We had not got to that point, given the same set of circumstances that we have today, which is basically the government springing it upon the industry in a budget measure rather than a medical measure.

I have a couple of questions. Can somebody clarify for me the number of scripts that are written in this country every year?

Mr Lindsay—I think it would be company by company. For Sanofi-aventis, there are approximately 300,000 patients who are treated with our oral bisphosphonates.

Senator FIERRAVANTI-WELLS—I just wanted to know the figure globally, Mr Lindsay. I thought it was about eight or 8.5 per person.

Mr James—I understand it is 8.65, according to the Australian Institute of Health and Welfare in 2007.

Senator FIERRAVANTI-WELLS—So, with 21 million people, we are talking about more than the 180 million scripts written per annum.

Mr James—Correct.

Senator FIERRAVANTI-WELLS—And the percentage of scripts in Australia that are issued to concessional holders is about 80 per cent—is that a correct assumption?

Mr James—About 75 to 80 per cent, yes.

Senator FIERRAVANTI-WELLS—Okay. So we are talking about 145 million scripts that are given to concessional people, many of whom are pensioners. I am trying to take this down to what the impact is on the public. Mr James, I pick up your point about the patients. I am actually trying to quantify the number of patients in Australia that are potentially going to be affected by this budget measure. That is what I am seeking your assistance on. We are talking about mental health drugs, and with increasing mental health conditions—I think the statistics are one in three for over-80s and one in two for over-90s—we are potentially talking about millions of scripts that could be affected for mental health patients. Am I correct in that assumption?

Mr James—Absolutely.

Senator FIERRAVANTI-WELLS—Okay. Because we are also talking about bisphosphonates, we are talking about a lot of older people.

Dr Condoleon—That is correct. Over 2.2 million Australians are affected by osteoporosis. There is a need to increase awareness. There are currently around 300,000 patients on bisphosphonate treatment out of that total group. There is a high burden of disease. Fractures resulting from osteoporosis cost the economy almost $2 billion per year, so making treatment simple and accessible is important to manage that condition.

Senator FIERRAVANTI-WELLS—Of course, a lot of this medication would also be dispensed in nursing homes, so given the crisis in aged care at the moment we are potentially adding another burden to the aged care sector for a whole range of different issues.

Dr Condoleon—That is correct. Osteoporosis is a condition that increases with ageing. I think it is important to point out that, if I take hip fracture as one of the most debilitating results of osteoporosis, up to a quarter of elderly patients who suffer a hip fracture can pass away within a few months, up to a quarter will be put in a nursing home for the remainder of their lives and up to half will never regain mobility. So having effective treatments in this space is critical, and making them accessible and easy to use and raising awareness are obviously in all our interests.

Senator FIERRAVANTI-WELLS—How much do you think that this measure is actually going to end up saving the government? Can anybody give an assessment of this?

Mr Lindsay—In the Department of Health and Ageing statement, it has been estimated that these therapeutic groups would save about $160 million over four years.

Senator FIERRAVANTI-WELLS—Okay. That would potentially put at risk millions of Australians for the sake of $150 million or $160 million. Given the billions of dollars that this government is wasting at the moment, we are here talking about the lives of Australians for the sake of $150 million or $160 million. That is it in a nutshell, is it?

Dr Fisher—We are also here talking about that small amount of money and introducing risk into the clinic in a prescribing decision. What the pharmaceutical industry has done is to work in consultation with government to deliver over $8.5 billion in savings without introducing risk into the clinic.

CHAIR—Senator, I remind you that you have two minutes of your time left.

Senator FIERRAVANTI-WELLS—We are, Dr Fisher, talking about potentially the most vulnerable in our community—people who suffer from mental health conditions or depression. In particular, a lot of them are older people. Could you please take this on notice: given the uncertainty surrounding the accepted definition of interchangeability—you heard the questioning of Medicines Australia—what do you suggest is a sound definition of 'interchangeability'? Also, what do you consider should be a fuller, more independent analysis of all clinical evidence that should be taken into consideration when medicines have to be determined as interchangeable? I am picking up particularly the point in the Sanofi-aventis submission. If you could take those on notice, I think that would be very helpful to the committee.

Mr Lindsay—There is a definition provided by the Department of Health and Ageing within their Pharmaceutical Benefits Pricing Authority manual, which is a manual given to industry to help them when they are putting pricing submissions forward. The definition of 'interchangeable' in that manual is that it:

Refers to brands of a pharmaceutical item with a particular strength (and brands of related pharmaceutical items) where evidence of bioequivalence or therapeutic equivalence … on an individual basis … has been accepted by the TGA.

'Bioequivalence' basically means it is the same chemical entity. With all these therapeutic groups, they are not the same chemical entity; I think we have established that. But, to our knowledge, the TGA has never been approached to comment on whether these groups are interchangeable. We do not know if the PBAC has used that definition or not. It is just a definition which is out there from the departments.

Mr Miles—The PBAC, at its meeting in March of this year, made a determination in relation to two versions of exactly the same molecule. I am talking about not one of our products but Mobic, which is an arthritis medication. The PBAC stated that the capsule version and the tablet version of exactly the same molecule were not bioequivalent and, therefore, not interchangeable. These are the PBAC's own comments from its minutes of this year, saying that the same molecule in two different forms is not interchangeable. We are at loss as to understand why two different molecules in different medications are.

Senator MOORE—Dr Fisher, in your evidence you said you were forced to make a certain decision as a GP. Why did you have to make the decision that you described?

Dr Fisher—The relationship between doctor and patient is sacrosanct, as you know. The critical point of making a prescribing decision should be made on clinical and medical grounds only. To introduce any other factor, such as price, into that decision making must increase the risk of an inappropriate decision and, therefore, the risk of a potential—

Senator MOORE—So why was that your decision? My point is that the doctor prescribing is the person who makes the prescribing decision. There are a whole lot of factors that you have to talk about with your patient, but the final decision as to medication is with the doctor. Does this legislation change that?

Dr Fisher—This legislation introduces a cost factor, which will inevitably, in a number of clinical situations—and taking into consideration the senator's point with regard to our most vulnerable community members being the most likely to be affected by this policy—be a lever which will affect a prescribing decision.

Senator MOORE—But the end decision is still with the physician.

Dr Fisher—The end decision is a partnership between physician and patient.

Senator MOORE—Dr Stewart made the point that physicians are confused by dosages and that currently, with all pharmaceuticals, there are clear guidelines on dosage. Part of getting listed is having those clear indications. If a physician seeks out the information, why would they be confused about dosages?

Dr Stewart—Hypothetically, because doctors look up to the PBAC as a respected body that has said two drugs are interchangeable, if a doctor is not across the detail they might switch a patient from one drug to the other in a more arbitrary kind of fashion. If a patient comes in and says, 'I'm not enjoying taking this medicine because the pills are too big,' normally a doctor might be dissuaded from saying, 'We'll try you on something else.' But now he might think, 'The PBAC has said these two drugs are the same, so I'll switch you from your big pill to a smaller pill. Because you're on 20 milligrams of this tablet, I'll switch you to 20 milligrams of the other tablet,' not realising that he has to switch to three times that strength. That sort of decision is a decision that may be made.

Senator MOORE—That seems to me not to be the right thing to do if you are a doctor. Under current situations, not taking into account any of the changes, I would expect that they would have knowledge of what they are prescribing, down to size, shape and colour. Is that not so? Do they not have to have that knowledge?

Dr Stewart—They do need to have that knowledge, and generally speaking they do. But occasionally, particularly if the PBAC has mandated that the drugs are the same, they might switch more arbitrarily.

Dr Condoleon—We would go back to the determination that is being made. If we are in agreement that there is a lack of clarity of definition, a lack of criteria and a lack of consultation in the process—

Senator MOORE—If we are.

Dr Condoleon—If we are, then we are also in agreement that perhaps the advice that has been provided is not the right advice to guide decision making. If we can bring clarity to those steps, then we will all have confidence and we will remove the risk that currently we are highlighting in different patient groups.

Senator MOORE—I totally accept the need for clarity, but I would expect that doctors would actually know what they are prescribing. Doctors change medication all the time, particularly with mental health patients. I take the point absolutely, Mr James and Mr Lindsay, that doctors are constantly looking at ways to change medication to fit better with the person they are dealing with. So there is a lot of change happening already; your argument is that this process could make the change more difficult.

Mr James—Particularly in relation to mental health patients, our point is that, when a mental health patient is stabilised and when that treatment is working for them as an individual, then there should be no cause for change driven by cost, policy or otherwise.

Senator MOORE—I would like to get some information from you on notice as to the exact cost difference of the changes in terms of the drugs in your examples. I know you cannot do everything, but each of you has come to the table with a particular case in mind. If I could get some dollar figures around that on notice, that would be very useful.

CHAIR—Thank you very much. If you could get your answers to questions on notice to the secretariat, that would be very much appreciated.

Proceedings suspended from 9.47 am to 9.59 am

AIESI, Ms Sue, Policy, Communications and Research Manager, Carers Australia

BESWICK, Ms Jessica, Policy and Research Officer, Carers Australia

CAHILL, Ms Ainslie, Chief Executive Officer, Arthritis Australia

CANTWELL, Ms Melanie, Deputy Chief Executive Officer, Mental Health Council of Australia

CROSBIE, Mr David, Chief Executive Officer, Mental Health Council of Australia

DONOVAN, Ms Janette Anne, Member, Chronic Illness Alliance

McDONALD, Dr Elizabeth Anne, Medical Director, MS Australia

MARABANI, Dr Mona, President, Arthritis Australia

SEIBEL, Professor Markus Joachim, Council Member and Member of the Therapeutics Committee, Australia and New Zealand Bone and Mineral Society

Evidence from Ms Donovan was taken via teleconference—

CHAIR—Welcome, everybody. Most of you have appeared before the committee before and know the process. I understand each of you has been given information on parliamentary privilege and the protection of witnesses and evidence. We are waiting to connect with Ms Donovan by teleconference, but we will start because we all know time is very limited today. We have all your submissions, thank you very much, which we have read. We have a limited amount of time for the roundtable, so what I would like to do is invite any or each of you to make a brief opening statement and then we will get into questions, if that is okay. Who would like to start? Professor Seibel, I know that you have to go slightly early—

Prof. Seibel—Yes, sorry about that.

CHAIR—so would you like to start?

Prof. Seibel—Sure. I am happy to do that. As you know, I represent the Australia and New Zealand Bone and Mineral Society here, a society that acts as the principal professional body for scientists and clinicians involved in research and management, obviously, of patients in the field of metabolic bone disease. As regards my professional background, I am an internist, a clinician and a scientist, so I do understand the needs of patients—I see patients myself almost every day—but I also know how to interpret scientific evidence in this area.

The ANZBMS recognises and understands the need to control the cost of health care wherever possible and justified. The society appreciates that the government has an obligation to reduce costs to the health budget and fully supports these efforts. The ANZBMS does assume that the

Australian federal government bases its therapeutic group policy on a strict evidence based approach and that medicines are only placed in the therapeutic groups after rigorous assessment.

In respect to this proposal, particularly the one in terms of bisphosphonates, oral bisphosphonates—I should be specific here—the main assumption really is that all oral bisphosphonates are equal to generic alendronate, which is one of many available oral bisphosphonate forms here in Australia, and that the choice of oral bisphosphonate will make no practical difference to the patient or their subsequent health outcome. So the relevant question here is whether the currently available branded and generic oral bisphosphonates are indeed clinically and pharmacologically equivalent to generic alendronate, which is, if you like, the benchmark in terms of monetary considerations.

Based on the available evidence, which I think and the ANZBMS considers robust, well documented and science based, the ANZBMS has come to the conclusion that the oral bisphosphonates currently available in Australia, including alendronate and risedronate alone and in combination with calcium and/or vitamin D—and you have seen the range of medication available previously—are not interchangeable at a patient level. The ANZBMS maintains that, from a scientific and clinical perspective, several substantial differences exist between alendronate and risedronate, and between generic alendronate Fosamax and Actonel, which are the branded oral bisphosphonates available. We maintain that these differences can impact on patients' compliance and persistence with therapy and effective fracture reduction.

Having said all of that, I would like to come back to the definition of 'interchangeability', which really is at the heart of the discussion here. I have been searching high and low for a definition of 'interchangeability', and the closest definition I came to was that by the Australian TGA, where they talk about 'essentially similar drugs' and they orient themselves by the European or EC guidelines. There are three criteria here—very clear, specific criteria. They say that (1) 'essentially similar drugs' have the same quantity and quality composition in terms of active principle and (2) that they have the same pharmaceutical form—for example, tablet form, which is the case. Thirdly, and this is important, I think, 'essentially similar drugs' are bioequivalent unless it is evident from scientific knowledge that the medicines differ significantly as regards safety or efficacy.

Interchangeability, on a scientific definition, is bioequivalence or therapeutic equivalence. If you go to Wikipedia you get another definition—that is, that 'drugs have the same effect in the patient' or 'a condition in which exist two or more items with characteristics making them equivalent in performance and effect'. If you look at alendronate and risedronate, the two oral bisphosphonates in question here, you see that there are a number of characteristics which clearly set them apart from each other. I will very quickly go through these. I do not want to take up too much time here. If you look at figure 1, in terms of binding affinity and enzyme inhibition—I do not want to bore you with the scientific details—you can tell that RIS, which is risedronate, and ALN, which is alendronate, have significantly different binding affinities to bone and also the inhibition of the enzyme which actually leads to the effect is quite different. As you can see here, ALN and risedronate have very different effects with risedronate being a much weaker inhibitor of the enzyme.

I would like you to look at figure 2. You will see a number of lines there which really just look at the different effect of risedronate versus alendronate. This is one of the very rare studies we

have where two drugs—and fortunately just exactly the drugs in question at this inquiry—have been tested head to head. We do not have a lot of these studies and this is an essential piece of information in regard to the question here. So as you can see, in all parameters measured—and this is just bone turnover, which is a measure of how bone remodels—risedronate suppressed bone turnover less than alendronate and this difference was at every time point significant. There are significant differences in the effect of those two substances in terms of biological effect and therapeutic effect. It is very important to notice that.

I did not bring a figure here, but I can assure you that we know from other studies that the onset—that is, how quickly that drug works in a patient—and the offset—that is, how fast the effects on bone turnover or fracture risk disappear when you stop the drug—are significantly different between risedronate and alendronate. Risedronate has a fast onset and a fast offset. Alendronate is like an ocean steamer with a slow onset and a very long offset. That has practical consequences in terms of how we choose a drug for which patient.

CHAIR—Prof Seibel, I am conscious of time and we have a number of represents here who want to make a statement.

Prof. Seibel—I am basically done. If you just go to the next figure I would like to point out to you that apart from the scientific evidence which I have presented to you, we also have clinical evidence which clearly shows that you cannot lump together in one group an oral daily, an oral weekly and an oral monthly preparation because look at the differences in compliance. Patients do not like to take drugs every day. Compliance improved incredibly significantly—look at figure 3—when the weekly regimens were introduced. Again, now that the monthly regimens have been introduced—this is European data with the alendronate but it will be very similar for other monthly regiments—compliance has improved. You cannot assume that on a patient level these drugs are similar with similar effects, similar outcomes and similar compliance.

Dr Marabani—Thank you for the opportunity to attend and contribute to this inquiry. I am a rheumatologist with a practice in south-western Sydney. Arthritis Australia is a peak health consumer organisation. We have affiliated offices in every state and territory. Our prime responsibilities are awareness, education, research—we contribute almost $1 million a year to research into arthritis—and advocacy is a very strong component of our work. Arthritis Australia is not affiliated with any political party and represents the almost four million Australians living with arthritis, as well as their carers, their families and their friends.

Arthritis Australia's position and our purpose for submission to this inquiry are twofold. We believe that the criteria for biologic therapies, arthritis therapies for specific types of arthritis, should match worldwide clinical evidence and be relaxed to ensure that the right people have access to the right medication at the right time. The first of these drugs was listed on the PBS in 2002. They are not part of the new therapeutic groups at this time which are a subject of this Senate inquiry. We also believe that there is an urgent need for mandatory consumer consultation in all health policy reviews.

In our view, the PBS listing process—access guidelines and other restrictions—is not transparent enough because there is no mechanism for grassroots consumer input. A recent example of this is the PBAC review of the clinical effectiveness and cost effectiveness of the biological disease modifying anti-rheumatic drugs—often shortened to 'b-DMARDs', but today

I will refer to them as 'biologics'. These are therapies which have been proven to be life-changing for many consumers who have struggled over time with the debilitating and permanently damaging effects of inflammatory arthritis like rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis. A recommendation of this PBAC review is to alter access to these medications, including the introduction of a maximum of five PBS reimbursed biologics in a lifetime. We believe that widely recognised, high-quality clinical evidence for treatment using biologics has not been sufficiently taken into account.

I will give you a couple of examples of how these federal policies may impact on the people I represent. Firstly, please consider a patient with severe rheumatoid arthritis diagnosed in their 30s. This limit of five biologics might mean that people who are very severely affected will be consigned to a life of misery, with no effective treatments for another 40 or 50 years. This decision appears to discriminate against those with the most severe and aggressive disease. There are numerous agents in development now and no evidence to inform us on which drug will help an individual. In other words, it is a process of trial and error.

Secondly, the PBS criteria for psoriatic arthritis include a requirement that a consumer must have 20 joints actively affected by the disease to qualify for biological therapy under the PBS. In my practice, I treat many patients who rarely have 20 inflamed joints. However, I am unable to prescribe a biologic to treat those people. For example, a man who springs to mind who has a badly inflamed right knee and several joints in his right hand cannot work but I cannot help him because he does not meet the current criteria for PBS subsidy for a biological agent.

Lastly, people with ankylosing spondylitis, a disease which causes severe spinal pain and disability, and for which there are no standard drugs available, cannot access effective biological therapy until there is severe damage visible on plain X-rays or CT scans, even if there are visible signs of active disease on other types of imaging such as MRI. This serves to delay access to treatment and such delays compound disability.

A 2007 Access Economics report states that the cost of arthritis to Australia is $24 billion, 60 per cent of which is borne by the consumer. Many of these Australians are on fixed incomes such as pensions or disability support. As with my patients, they cannot possibly afford these medications without PBS subsidy.

We acknowledge that the new treatments for arthritis are expensive, but they are also very effective. We also know that there are growing numbers of biological therapies which have different mechanisms and which will advantage different people in different ways. Currently we have no way of knowing which agent will work for an individual. For example, a person with rheumatoid arthritis may respond to one biologic but not another. They are not interchangeable, even if they belong to the same class; and the same goes for side-effects. The Australian Institute of Health and Welfare publication *Medication use for arthritis and osteoporosis* says:

> Rheumatoid arthritis requires swift, early intervention. Clinical research has indicated that within the first 3 months of onset, this disease can cause irreversible deformities, considerably limit movement and reduce a person's life expectancy. The early diagnosis and immediate use of pharmacological agents such as DMARDs has been shown to reduce the impact rheumatoid arthritis has on a person's life.

It is for this reason I would like to draw your attention to the following concluding points.

First, rheumatoid arthritis doubles the risk of heart attack, increases the risk of infection by 70 per cent and reduces lifespan by 10 years. There is evidence that controlling disease can diminish these risks. Second, new restrictions for prescribing the biologics I am referring to, which will commence on 1 August this year, require failure of rheumatoid arthritis to respond to six months of standard therapy. This may be too late to save some people's jobs or independence. There are factors at onset which identify poor prognosis groups, and offering them early treatment may result in reduced morbidity and better outcomes. Also bear in mind that there are often delays in people accessing specialist care and diagnosis, which means that some patients will have had active disease for months before they are actually diagnosed.

Third, it is disappointing that full details of the proposed recommendations from the PBAC review of biologics were not discussed with Arthritis Australia. There is no process for direct communication with the PBAC. Consumer groups in other countries are invited to have formal input into the development and review of health policy. We would like to see this happen here so that policymakers are fully aware of the impact of their decisions and any unintended consequences.

CHAIR—Thank you. Mr Crosbie.

Mr Crosbie—Thank you for the opportunity to present and thank you for your interest in this area. I have to say, in terms of the broader context, that the National Medicines Policy is a critical component of all mental health considerations. One-fifth of all medications prescribed by doctors are for mental health; for anxiety, depression or antipsychotics. For people with mental illness, the most common response, the most common treatment and the most common ongoing treatment regime, is invariably some form of medication. And the most common reason why people are readmitted to acute settings is either a failure to comply or a change in medication. So medication is a very central part of the way we respond to mental illness in this country. We also acknowledge that the National Medicines Policy goals are goals that we would share. Generally, I think Australia does quite well in terms of its PBS in comparison with the experiences of people in other countries. In many ways we have a very good system, and what we are talking about today is ways of improving that system rather than suggesting that we need to lose the core elements. For us, cost and access, safety and quality, and quality use of medicines are really critical, as are the viability and responsibility of pharmaceutical companies. We support those goals, we support the National Medicines Policy and, in broad terms, we support the PBS.

One of the major factors with having a mental illness, of course, is that you are likely to be disengaged from work. A high proportion of people are on disability pension, and affordability is a very significant issue for people. In fact, there is research from SANE and others showing that people with a mental illness have to make the decision at times between being able to access their medication and being able to buy food, pay the rent or pay other bills. That is a very difficult situation and a very difficult decision for many people. So for us cost is a really critical factor, and measures to try to reduce cost are ones that we strongly support. But the difficulty of balancing the need to reduce cost against the issue of interchangeability is quite complex.

Again, mental illness is a little bit different from some other diseases in the sense that it is harder to measure the impact of medications in a controlled way. With some medications and some diseases, it is possible to measure range of motion, size of growth or other kinds of impairments. The nature of mental illness is that it is inconsistent in terms of symptoms. It is

episodic and changes from situation to situation. It is also not something that can be easily measured. It is really about people's experience. It is about the way they are experiencing the world. Often that is very difficult to accurately assess, which in this country, and in countries around the world, often makes assessing the most appropriate medication a bit of a hit-and-miss exercise. I think many consumers will talk about their experiences of trying to find the right kind of medical regime, treatment, medication and dosage and about the way that changes over time. We know that the way people respond to medications varies enormously. What works for one person presenting the same symptoms as someone else may not be applicable even though they have the same symptoms. So mental illness is quite complex in that sense in terms of trying to get the medications right.

The other thing to say about mental illness is that it often coexists with physical illness. Many people who have a mental illness also have diabetes or will suffer other physical diseases such as arthritis. When you look at the six million hospital bed days that are attributed to mental illness, only half of those are attributed to people who present with mental illness; the rest are because mental illness complicates the other diseases.

So we think there is a case for arguing a much greater level of engagement with consumers and a more specific mental health focus in the National Medicines Policy, whether that is a subset of the National Medicines Policy or an area of the National Medicines Policy which can be developed more fully. At the moment, we are concerned that the level at which decisions are made, including decisions that we are now discussing about the groups, is inadequate in terms of properly consulting people who experience mental illness and people who work with people who experience mental illness.

I do not want to take up too much time, except to say that unless there is a recognition of the complexity of the relationship between medicines and the treatment of mental illness, and unless there is engagement with the people who are engaged in that relationship—particularly consumers, their carers and the people who are involved in trying to find the right kind of treatment for people—we worry about the trade-off against cost and accessibility. Cost and accessibility are really critical, but if we are going to trade off access to medicines or interchangeability of medicines then it needs to be done in a way that engages with people who are the direct experiencers—the consumers and the people who are trying to deal with a mental illness—and the people who are working with them. Thank you.

CHAIR—Thank you. Who is next?

Ms Aiesi—I am from Carers Australia, and we represent the people who care for people who are on medications. They provide a range of care and support, from personal care through to managing complex medication regimes. Any changes to therapeutic goods can therefore have a significant impact on the lives of carers and on the lives of the whole family. It is about the impact on not just the individual who is on the medication but also the whole family.

The National Health and Hospital Reform Commission have identified carers as the invisible health workforce. They should be seen as part of a healthcare management team; often they are not. We believe that carers have extensive knowledge of the person that they are caring for and that, if there are going to be any changes to a medication regime, carers need to be involved. There are many people in our society who do not have the capacity to manage their own

medication and rely on the assistance of family carers to ensure that their daily medication needs are met. If we are going to change a medication dose from weekly to daily or hourly, carers need to know this because they are the ones who manage it in the home.

Caring can be intensive and demanding, and it usually takes place alongside medication management and a whole range of other tasks. Primary carers spend on average more than 40 hours per week caring for a person with a profound or severe core activity limitation. Individual carers on average contribute 104 hours per week caring for a person with a mental illness. That is often because of the episodic nature of mental illness.

We believe there are a number of issues that need to be considered in all of this, including, as has been mentioned by Mr Crosbie, cost. The cost of any changes to medication will have a significant impact not just on the consumer; it can also have an impact on the whole family. As Mr Crosbie said, it is often the difference between filling a prescription and putting food on the table for a family. We are really, really concerned. We have solid evidence that people who are carers do not look after their own health; they cannot fill their own prescriptions. We are really concerned that increases in cost will reduce accessibility.

We know that carers are often left out of treatment decisions involving the person they care for and they are often not recognised as part of the care team, even though they have expert knowledge on how a patient reacts to a medication because they are there every day. So we believe that, if you are looking at any change to this, there needs to be extensive consultation with consumers that includes family carers.

As I said, the financial aspect of any change is the main concern for carers. I just cannot stress enough the absolute crisis that such a change can put a family in. Not all carers are on carer payment. We have carers who are living in single-income households, which could be $59,000 a year, and increasing any costs will have a really bad impact. It is clear that all carers take on the risk of a number of poor life opportunities when they become carers, so they cannot afford any further risks to their health and wellbeing or negative impacts on their capacity to provide care.

The unique perspective of carers has to be taken into account when we are looking at any changes to the PBS. They are probably as aware as most health professionals of the impact of drugs on the person they are caring for. We know that, if there is a change in medication, particularly around mental illness, and the carer is not aware of it, it can have really serious consequences. So we would just ask that, when you are looking at changes in this area, you take the whole family into account and ensure family carers are part of the consultation process.

Ms Beswick—I would like to support Suzanne's statement with a case study. At Carers Australia we strongly believe in the importance of hearing carers' own stories. So this is the story of the carer we have been in contact with. It illustrates the high cost of care from many caring families. This carer is caring for her son who has severe autism. Her husband had a stroke but has, with assistance, being able to return to work in a government position. They are not, therefore, eligible for carer payment, although she does receive carer allowance and he is on an ASO5 salary. She is only able to work irregular hours, generally a few hours a month, and the household income is therefore quite low. They struggle every day just to meet their daily living costs but this lady is absolutely fantastic. She is great at managing the household budget. For example, she never buys food that is not on sale. She buys in bulk when there are specials. She

preserves food and she freezes food. Even with all this, she is not able to afford proper health treatment for herself. She generally puts the needs of her son and her husband before her own health concerns. Her son is on extensive medication and, even though he is now 10, he is still in diapers. This has an enormous daily cost and annual cost which must be taken into account in the household budget. That is just one example of a caring family where any increase in the cost of medication will be detrimental to the long-term health of everyone in the household.

Dr McDonald—Thank you for inviting representatives of MS Australia to the Senate inquiry. I would like to begin by giving a brief overview of MS and highlight the role of pharmaceuticals in this disease, together with a brief overview of the issues faced by people with MS in regard to access to pharmaceuticals. MS is a chronic progressive, disabling, neurological disease of the brain and spinal cord. We think it is affecting about 21,000 Australians and three times as many women than men are affected. MS is complex and unpredictable and people can experience a plethora of symptoms—physical, sensory and cognitive. More typically, MS starts as a relapsing remitting type of disease and after 10 to 15 years it becomes a secondary progressive evolution with a steady accumulation of disability, although some 10 per cent can be progressive right from the start. MS is diagnosed more in young people, in their 20s and 30s. There is increasing awareness now of childhood MS. In fact, the MS International Federation has rated research into childhood MS as one of its top research priorities.

A 2005 Access Economics report estimated that the total cost of MS to the Australian community was greater than $600 million, of which $117 million was allocated to health costs and the largest component of this was pharmaceutical costs—$72 million. Also, with research through MS Australia, we have found that people with MS tend to have lower participation in paid employment compared to those with other chronic diseases and, of course, compared to the general population. This is not just an economic problem for us; it greatly affects the quality of life for those with the disease, their families and their carers. A recent Australian study published in the *Journal of Neurology* this year looked at longitudinal changes in employment and showed that the main reason people came out of employment or lost their jobs was ineffective management of the symptoms; it was not due to workplace factors. I think this is really important when we are considering pharmaceuticals. The most frequently listed symptoms were fatigue and issues relating to mobility and cognitive deficit. Maintaining employment will not only reduce the individual economic burden and keep people off government subsidies but will help with the economic societal burden.

What is the role of pharmaceuticals in MS and why are they important? Over the last decade, new treatments for multiple sclerosis have become available for MS, the disease. These are the injectable immunomodulating medications. The first one, betaferon, became available on the PBS in 1996. They reduce the relapse rate and prolonged the time to onset of disability. They are not a cure. The current PBS criteria stipulates two episodes in a two-year time frame, which is contrary to the latest scientific evidence indicating that the earlier treatment is commenced the better the outcome. Reducing episodes, delaying disability, has long-term positive consequences. With these medications and with new ones coming on board I think we are going to see a change in the natural history of multiple sclerosis. This is a disease which people have for decades, not just for a short period of time.

The other areas where pharmaceuticals are playing an increasing role are in the management of the common MS symptoms such as pain, fatigue, spasticity and erectile dysfunction, for

example. Neurogenic pain, not the muscular skeletal pain caused by disability, can be effectively treated with gabapentin and antiepileptic drug but it is not available for this indication on the PBS. That is a major issue for us. Similarly the use of modafinil for fatigue, a hidden disability of MS experienced by about 80 per cent of people, is also not listed on the PBS for this indication. Erectile dysfunction due to neurological impairment in MS is an intrusive symptom for men of this age and their partners and can be successfully treated with PDE5 inhibitors such as sildenafil but it is not available on the PBS. Of particular concern are the reported deaths of individuals who have obtained contaminated erection medications via the internet, which is a tempting proposition given the high cost in Australian pharmacies. Intrathecal baclofen pumps are a key treatment option for those with intractable spasticity who are not successfully treated with oral medications, but also these are not subsidised and are way beyond the affordability of the majority of people with MS. Oral medications for disease modulation are in the pipeline and, given safety and efficacy considerations, ease of access for people with MS is advocated early in the disease's course.

In summary, I would like to say that the chronicity and disability of MS makes it a costly disease in terms of care requirements, treatments and lost productivity, and I think we need to look at the global picture when we look specifically at the PBS. Improving ease of access to medications that will make a difference will have far-reaching consequences. I agree with the other speakers today that consumer consultation from the outset is important. Just to summarise also, a person who has MS does not mean that they exclusively have MS and nothing else. People with MS with a chronic disease age are going to get the other diseases as well. So everything that has been said by other medications comes to play as well.

CHAIR—Ms Donovan, are you still there?

Ms Donovan—Yes, I am here.

CHAIR—Thank you for being so patient with us and I am sorry that we could not get you on board at the beginning. I would like to check that you did get information on parliamentary privilege and the protection of witnesses in evidence.

Ms Donovan—Yes, thank you.

CHAIR—I invite you to make a brief opening statement and then we will have a limited time for questions.

Ms Donovan—I am a member of the Chronic Illness Alliance and I am representing Christine Walker, who is the executive officer, and is unable to be on the teleconference this morning due to family commitments. My membership of the alliance was spurred by the fact that I grew up in a family with multiple chronic illnesses and have participated in caring for one of those family members over a long period of time. Is it okay to go straight into my statement?

CHAIR—Yes, please, and I am really sorry to have to ask you to keep it fairly short as we have a limited time for questions.

Ms Donovan—The Chronic Illness Alliance is the national group representing more than 50 consumer community based foundations that work with people with chronic illnesses. The aim

of the alliance is to minimise the social impact of chronic illnesses through education and information. Many of the people that the member organisations of the alliance represent and work with are people who have rare, long-term and multiple illnesses. However, with both clinical and social support, they may still be able to work and contribute to their communities. Medicines form an essential part of that support.

The Chronic Illness Alliance conducted research into the cost of chronic illnesses in 2004 and found that many people with chronic illnesses lived in poverty due to the costs of their illnesses, which in some cases exceeded 25 per cent of their income annually. The greatest contributors to those costs were the co-payments related to PBS medicines. With this in mind, the alliance would argue that many people with chronic illnesses cannot afford any increase in co-payments for PBS medicines. The view that most people can absorb a small increase in co-payments ignores the fact that there are co-payments or full payments on nearly every service they receive from federal, state based and privately provided services.

Out-of-pocket costs for health care in Australia are now some 30 per cent of the total costs. Many people with chronic illness therefore appreciate generic medicines when they are able to switch to them without affecting their health, as other submissions have covered. But they would appreciate it if they were substantially lower in price. The 12.5 per cent lower cost of generic medicines barely offsets all the other additional costs of being ill. The alliance notes however that the free trade agreement resulted in the creation of the F1 and F2 formularies, which broadly separate brand name medicines into F1 and generics into F2, cutting out the interchangeability between the two in terms of pricing. While there is a mandated need for price cuts to continue for F2 medicines—that is, the generics—there are no mandatory price cuts required for medicines in the F1 category—that is, the full-price medicines, which may not be PBS medicines. There is now even less transparency in pricing for the Australian consumer in relation to the PBS.

Many people with chronic conditions also have rare conditions and this enables them to access the orphan drug scheme. This is a great asset since most people with rare conditions would not be able to access life-saving medicines due to the sheer cost. However, in some cases further medicines are required and these are not always listed for the condition. For example, gabapentin is available to treat epilepsy but also has application for the treatment of neuropathic pain, but anyone requiring it for this purpose must meet the full cost. Similarly, sildenafil is available on the PBS to treat erectile dysfunction related to some conditions but not erectile dysfunction related to MS. It also has been found to have an application in primary pulmonary hypertension but people with this condition and men with MS must pay the full price.

CHAIR—Ms Donovan, I do not mean to cut in on you but essentially you are reading your submission.

Ms Donovan—Yes, I am.

CHAIR—We have got that and I am very concerned that we are running out of time. I am just wondering if you could conclude, because we have actually read your submission.

Ms Donovan—Okay. In conclusion I will come back to the first point of the submission. People with chronic illnesses cannot afford any increase in co-payments for PBS medicines. As I

have already stated, many of them have multiple conditions and they are already often paying full cost for both medical treatment and other treatments through allied health. Thank you for listening to me this morning.

CHAIR—Thank you.

Senator FIERRAVANTI-WELLS—Professor Siebel, should I infer from your comments that you think that the TGA definition that you referred to would be a sound definition of interchangeability? If not, what do you think should be the definition? If you do not want to elaborate today, please feel free to give us a considered written response.

Prof. Seibel—Personally I think it is a good start. It probably needs some more consideration. If you go and have a look at the FDA public access database, they define approved drug products with therapeutic equivalents on their webpage. They have a full list of the drugs that they consider interchangeable and alendronate and risedronate are not considered interchangeable at the FDA level. I think the TGA definition is a good start. I would like to ask that the ANZBMS can submit a suggestion for an operational definition to help.

Senator FIERRAVANTI-WELLS—Dr Marabani, may I disclose at the beginning my patronage of AA Wollongong. It is something that I have had for some time and with bad knees I think I am going to need all of the drugs you are talking about. Do I detect that you really do see the need for a full review of the criteria that the PBAC adopts, and how do you actually see that practically working? Again, if you would prefer to take that on notice, please feel free to do so.

Dr Marabani—I would like to consider that as it is a very big question. I would be happy to respond to you in due course.

Senator FIERRAVANTI-WELLS—Mr Crosbie, in terms of the statistics in relation to mental health, the drugs that we are talking about are going to have a major impact. I think you heard the statistics when we were talking about the number of scripts that are dispensed every year, and the proportion of those that are in the depression/mental health area is considerable. I do not know if you are able to put a statistical amount to that or if you would prefer to provide us with some statistics.

Mr Crosbie—I am happy to provide you with the specific ones that are encompassed in the group. There are 20 million prescriptions written every year for antidepression, anti-anxiety and antipsychotic drugs, which is one-fifth of all prescriptions written by doctors.

Senator FIERRAVANTI-WELLS—Of course, given the statistics we heard earlier that about 80 per cent roughly are concessionals, we are talking about the most vulnerable in our society. In particular, in the case of the osteoporosis and those sorts of bone drugs we are talking about the frailest potentially as well. On the question of cost, one of the submissions made by one of the pharmaceutical companies in relation to Lipitor/Crestor, which was the example they used, the increasing cost doubled. It would go from $33.30 to $66.60 and for concessional patients from $5.40 to $10.80. So we really are effectively talking about a doubling in price. In picking up the example provided by Ms Beswick, in that circumstance when the doctor says to that family, or carer or patient, 'The drug that you're now on and that we have stabilised you on is going to cost double to you. The PBAC has told me that this is interchangeable and I can swap

it.' What do you think the decision is going to be in that instance? That is really what we are talking about, is it not?

Ms Aiesi—Sometimes what will happen in that case is that the family with wait until payday to fill a prescription. They may be without medication for two or three days until the next payday. That can have a really devastating effect on the patient and the family. People just really cannot afford increases like that; families cannot when they are on a single income and it is just devastating. It seriously is the difference between food or medication, often.

Senator FIERRAVANTI-WELLS—We are really talking about $150 million. This is the figure the pharmaceutical companies provided. You were not here before . The potential saving to the government is $150 million, but the additional cost, the social cost, down the track would far exceed that.

Ms Aiesi—It is not only the social cost. If people cannot afford to take their medication they are likely to end up back in hospital.

Senator FIERRAVANTI-WELLS—Yes.

Ms Aiesi—So there is an increased cost to the health system. While they might be saving money on pharmaceuticals, what is the actual cost to the health system? It just cannot be taken as a standard, 'We are saving you this.' That just does not add up.

Mr Crosbie—Senator, I think where interchangeability can be established, I do not see that we should be paying more for drugs than we need to.

Senator FIERRAVANTI-WELLS—Mr Crosbie, I am not questioning that. There is a process. This is really about the process. The reality, from the evidence that has been given, is that the process has been gone through to this point for what we are talking about today has nothing to do with health; it was really a budget measure. That is how it was announced. I gather you are coming from the patient perspective and that there might be a saving, but is this a saving that is ultimately going to benefit the patients that we are talking about? I think we are all in agreement in relation to that.

Earlier this year in the news we saw the case of Charmaine Dragun. You are probably familiar with the Channel 10 newsreader. Some of the reports referred to her having been diagnosed with depressive illness for 10 years and that she had been on antidepressant medication. One of the issues that I understand the coroner was looking into was whether the change in her medication had contributed to her death. The point that Ms Aiesi and you made was that the interchangeability ultimately comes down to the patient level.

Mr Crosbie—There are a couple of issues. I appreciate your interest in the area of mental health and interchangeability. It is a very significant issue, which is why we would support the notion that the process of working out what interchangeability is engages with people who are consumers of these products. We need to be very careful about talking about individual cases and we also have to be careful about talking about the contribution of medications to adverse events. As most of you would know, there are over 2,000 suicides in this country every year. There is a massive impact. Many of those people are on medications, and we have to be very

careful about linking those kinds of adverse events directly to medications. At the same time there is no doubt that the way medications are used has a massive impact on people's mental health and their capacity to cope. That is probably one of the major areas of mental health work—that interaction between a consumer and their prescriber and trying to get a stable medication regimen that does not have side effects or does not have side effects that cannot be tolerated. Unfortunately, in many ways it has become partly an interrogative process. It is about people working together. I suppose our key point is that we need to make medications cheaper wherever we can—I think we all agree on that. The question is about how much you trade off interchangeability. What we are all saying—although I do not want to speak for everyone—is that the process around determining interchangeability needs to factor in—even more than the scientific evidence—people's experience of using these medications and what it means to them in terms of the degree of interchangeability.

Senator MOORE—I have two questions and you may want to take these on notice. All of you raised the issue of consumer involvement. Professor, I am not sure whether you did, but everybody else raised the issue of consumer involvement in the process. There is a consumer member on the PBAC. What is the interaction that your groups have with that person? The PBAC is bound by confidentiality and all those kinds of things. I would like to know from the people who work with consumers all the time: what is the value of that position on the PBAC and how can it work? I think that is critical and it is part of a whole lot of different community affairs committee hearings that we have.

The second thing is whether you could consider the doctor-patient relationship in this process. You may have heard my questions to previous witnesses about the whole role of the doctor-patient relationship being critical in the area of medication. In an inquiry last week, the issue was raised about the doctor-patient relationship and how much conversation goes on about choice with consumers and their families. Would any of you like to give some information on notice about how often and how valuable these conversations are? We have heard that this could create more confusion—the drugs being grouped and the role of the doctor. It is about talking with your doctor—what kinds of issues come into it and how is price discussed? Perhaps you could give us something on notice about that whole process. The legislation does not say which drugs you can have but it does put the onus back on the discussion you have with the practitioner. You can take that on notice.

Professor, in terms of your area, we have had lots of evidence about that particular therapeutic group and how they operate. I value the contribution you added to that discussion.

CHAIR—If you could take those questions on notice, that would be appreciated. Professor, we know you have to go. I have one question which you may want to take on notice or you may be able to respond to it quickly now. I absolutely get the issues around interchangeability and the process, but are you saying to the committee that you do not think that the therapeutic group process is a good process at all? We heard from previous witnesses that they do not like it at all. Are you saying that you would think it would be better to get rid of that or are you saying that the process needs to be improved regarding interchangeability? I take on board the other issues about the slowness in decision-making et cetera. You may want to take that on notice or give a brief indication about where you sit on that, but we cannot enter into an extensive discussion.

Prof. Seibel—Very quickly, regarding therapeutic groups, if it is done with proper process and consultation, are perhaps a good way of cost saving. We acknowledge that we need to save on cost. There are also the other issues that have been mentioned. Access Economics has done quite an interesting calculation on what could be the effect of these therapeutic groups on osteoporosis treatments—oral bisphosphonates—in terms of compliance. The bottom line is that there would be new fractures costing us $300 million every year. So, is it a good process? In principle, it may be, but it has to be done the right way. Maybe there are better ways of doing this.

CHAIR—Does anyone else want to make a quick comment or are you happy to take the question on notice?

Mr Crosbie—The viability of the PBS is important. We have to look at costs and acknowledge that you cannot go on having a scheme raised by 10 per cent a year. In principle we support the notion of not having brand names that are equivalent drugs at different prices. Clearly we would support anything that could reduce costs to the consumer without having a negative impact on their treatment. I think the groups could go further, but the process around interchangeability and how that is done needs to be improved.

CHAIR—We have clearly got that message.

Ms Donovan—I would like to make a comment on that. In our submission we talk about the issue of generic medicines. The lower cost is around 12.5 per cent compared to nongenerics. I think there is room to look at lowering costs of generic medicines further. As well as looking at the process around therapeutic group premiums, which does have potential, in the future to save on the PBS, there are also further savings to be made through lowering the cost of generic medicines. The interchangeability issues are substantial, particularly for people with chronic illness, but the doctor-patient relationship and reporting adverse events is a very important component in that interchangeability issue.

CHAIR—Thank you very much. I thank all the witnesses. I am sorry it has been so rushed. We very much appreciate and value your time. Your contribution to the process is extremely important. Ms Aiesi, would you like to make an additional comment?

Ms Aiesi—When would you like these comments or this additional information?

CHAIR—In two weeks?

Ms Aiesi—Thank you.

CHAIR—That would be fantastic and very much appreciated.

[11.00 am]

O'SULLIVAN, Mr Vincent, Pharmacy Guild of Australia

RILEY, Ms Toni Elizabeth, National Councillor, Pharmacy Guild of Australia

TATCHELL, Dr Michael, Director, Health Economics, Pharmacy Guild of Australia

CHAIR—Welcome, and thank you for coming. I understand you have all been given information on parliamentary privilege and the protection of witnesses and evidence.

Dr Tatchell—Yes.

CHAIR—We have your submission, thank you very much. I would like to invite any one of you, or each of you, to make a brief opening statement. As you can see there is a lot of interest in this issue and there are lots of questions.

Ms Riley—We would like to thank you for the opportunity to present to this inquiry, and I will start with just a very brief statement. The Pharmacy Guild of Australia obviously represents the members and our members are owners of approximately 4,300 pharmacies out of the 5,050 community pharmacies around Australia. The Pharmacy Guild aims to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medication management and other related services.

The Pharmacy Guild supports the concepts of therapeutic groups as they are an effective way for the government to achieve value from the PBS without affecting patient outcomes and it is important to us that patients are always able to access the most appropriate medicines for their needs at no extra cost. We note—and it has not been mentioned today—that a prescriber can apply for an exemption from the therapeutic premium. That is an option for the prescriber at the time.

The Pharmacy Guild believes that the PBAC is the most appropriate body to determine therapeutic groups but would welcome more information being made regarding the process and the basis on which it makes its decision. This would improve stakeholder confidence and, obviously, transparency in this policy. The Pharmacy Guild also believes that prescribers need to be provided with adequate information regarding therapeutic groups and extension mechanisms so they can make appropriate prescribing decisions. That is all the statement we would like to make and we would welcome questions.

Senator FIERRAVANTI-WELLS—In your submission, page 5, you point out that:

… patients and prescribers are not always aware of these mechanisms and this may sometimes lead to unnecessary confusion or patients paying the TGP when they may not need to do so.

There is often confusion amongst stakeholders …

Can you comment on what you perceive to be the increased likelihood of patient confusion with this whole process?

Ms Riley—I guess the confusion issue is around the cost and a different drug being prescribed and ultimately dispensed. I think that in all the conversations previously we have omitted to consider the involvement and the importance of the pharmacist in this process. Every prescription that is written by a doctor is actually dispensed by a pharmacist and at that time, prior to dispensing that prescription, the pharmacist will be checking that patient's previous history of medications and, if noting that it is something different, having a conversation with that patient. Many times in my pharmacy I have had conversations with people about therapeutic group premiums. They have not known about them. The doctor has not mentioned them so, as an advocate for the patient, the pharmacist will often make a phone call to the doctor to try to sort something out if it is possible. Sometimes it is and sometimes it is not, but I do not believe that doctors are fully aware of the exemptions that they can apply.

Senator FIERRAVANTI-WELLS—But, of course, it is important that you then look at how the process works. You ring up somebody—I think it is Medicare now—and probably the person on the other end of the line who is going to give you this exemption is not going to be somebody with a medical background. Correct me if I am wrong. It is all very well, Ms Riley, to talk about the exemption, but somebody who is not medically qualified is effectively going to make a decision about a patient and the interchangeability of medication when they know absolutely nothing about it.

Ms Riley—I agree and disagree. I totally agree that approval for any kind of authority is given by nonmedical people. The doctor, when obtaining authority, has to answer some fairly set questions. The doctor usually would know what those questions will be. The doctor actually makes the prescribing decision before ringing up for an authority. When applying for an authority for an exemption, the doctor has already made the decision to prescribe drug A rather than drug B. Drug A has a therapeutic group premium on it. The doctor then can, if he or she so chooses, ring the authoritative people and ask for an exemption on that premium. As our submission says on page 3, there are several reasons doctors can do this: adverse effects occurring with all the base price drugs, drug interactions being expected to occur and the possibility that transfer will cause confusion. Those are the conditions under which the doctor can apply for an exemption for that premium. Whether or not the doctor chooses to is entirely the doctor's decision. It is often not done, though.

Senator FIERRAVANTI-WELLS—Ultimately—and you heard the evidence—when faced with a patient, if the PBAC has made a decision that drugs are interchangeable, the doctor would probably turn around and say something like this: 'These two are interchangeable. This one's cheaper. Do you want to change?' Correct me if I am wrong.

Ms Riley—I totally agree with you.

Senator FIERRAVANTI-WELLS—When all is said and done, in busy practice—and I do not mean this in any negative way against the medical profession—the reality is that cost is an important factor.

Ms Riley—Sometimes it is, and sometimes it is not. I can cite examples from my own practice where the doctor said to the patient: 'There is a cheaper drug. Would you like to take it? It's slightly different to the one you're taking, but you're going to have to pay a premium on the one you are taking.' I have numerous patients who say, 'I will continue taking what I know.'

Senator FIERRAVANTI-WELLS—I know. But if, in the situation we are talking about, somebody has determined that two drugs are interchangeable—

Ms Riley—I am talking about products that already have therapeutic group premiums on them. This policy has been around for some years now. The first groups were announced in 1998. There are many drugs in those groups—not as many as in other groups, but there are many drugs that have premiums on them—and patients do choose, against doctors' better judgment, to some extent, or with their better judgment, to stay on those drugs. People do have the choice, and the doctor has the ultimate choice as well.

Senator FIERRAVANTI-WELLS—There has been a lot of discussion today about the process of the formation of therapeutic groups. You have obviously watched this process—and I think this process is differentiated from the previous process, in 1998—

Ms Riley—Very much so.

Senator FIERRAVANTI-WELLS—Very much so—thank you. That is very much the case. You have obviously observed this process. Do you wish to comment at all about how you saw the formation of these therapeutic groups and whether, in your view, appropriate clinical data was taken into account in reaching that conclusion?

Ms Riley—In my view—and this is very much my view—we have no idea of how they were reached. We have no idea what data was considered. We know there was no consultation with us. I have to say that I am very concerned about how they arrived at the decisions, but I do not know how they got there, and nobody is prepared to say. The lack of knowledge and the lack of transparency are of great concern.

Senator FIERRAVANTI-WELLS—Given the scope of the sorts of drugs that we are talking about, they are going to have quite a wide impact in the community.

Ms Riley—Without a shadow of a doubt, especially the mental health drugs.

Senator FIERRAVANTI-WELLS—Exactly. Interestingly, the drugs that have been identified in this process, and given the growing level of mental health issues in the community and in particular the growing needs of an ageing population, cover two of the areas that are being targeted as part of this budget measure.

Ms Riley—Yes, I totally agree with you. It is of great concern. The lack of consultation and the lack of any indication as to how these decisions were arrived at are of concern to us.

Senator FIERRAVANTI-WELLS—I have asked the question about the definition of 'interchangeability' previously. Does the guild have a view about what would be an appropriate definition for 'interchangeability'?

Mr O'Sullivan—We are happy for the PBAC to make that decision. However, we would welcome greater transparency in the decision-making process.

Senator FIERRAVANTI-WELLS—You would have heard the evidence that we discussed. I trawled through the various provisions of the National Health Act in relation to the absence of a definition. Have you gone so far as to give some thought to where you perceive there to be legislative deficiencies that this committee should give consideration to addressing?

Mr O'Sullivan—Not really. We rely on the PBAC to make that decision. We just think it should be transparent.

Senator FIERRAVANTI-WELLS—How do you think it should be transparent?

Mr O'Sullivan—The PBAC meeting minutes could be publicised. Maybe the submissions to the PBAC could be made public, as in this committee—all the submissions were made public on a website. I think that would increase confidence in the process for the stakeholders.

Ms Riley—It is even simpler than that. We have no idea how they go through the decision-making process. There are no published guidelines as to how this decision was arrived at.

Senator FIERRAVANTI-WELLS—That is the point that I was trawling through today. In this case the minister made the decision is part of the budget process. There was obviously a six-month period where that decision was kept under wraps. The decision was made. It was announced in the budget context, not in a health context, without any consultation with anybody, it seems, and then we get two paragraphs from the PBAC—Mr Miles from Pfizer showed them to us this morning—and that was it.

Ms Riley—If an outcome of this inquiry is that we get some guidelines and we know how these decisions are arrived at, we have gone a long way.

Senator FIERRAVANTI-WELLS—Of course, comparing and contrasting the volume of material that is required for the listing of a product on the Pharmaceutical Benefits Scheme and all the processes that one has to go through. Earlier it was mentioned that there are 30,000 pages of documentation.

Ms Riley—It is an unenviable task that the PBAC have. It is a very important task, but they are making decisions based on cost effectiveness and the effectiveness and safe use of the drug. I believe that when they listing drugs they are looking at a particular drug and they are looking at it with reference to the other drugs currently on the PBS.

Senator FIERRAVANTI-WELLS—With the population criteria.

Ms Riley—Yes. But this is a completely separate issue. This is about grouping things, lumping things together, because they appear to be the same. That is a different decision. It requires different information and different interrogation of data. If we do not know what they are doing, how do we have total confidence in it?

Senator FIERRAVANTI-WELLS—Particularly in this case, a decision was made because of this process intervening, but otherwise it happens, decisions are made, changes are made and patients' medication is changed, and then there is a period in the community when the effects of the interchangeability are seen. Potentially down the track, Mrs Bloggs, who has relied on the advice of her doctor and made the decision to change to another drug, suddenly finds herself at risk. How many Mrs Bloggses do we have to wait for to potentially have adverse medical conditions before we do anything? That is my concern.

Mr O'Sullivan—I think that Mrs Bloggs can stay on her medication; she does not have to change. Say, for example, she is on Crestor, she does not have to change to Lipitor. There are mechanisms where, in consultation with her prescriber, she can stay on that particular drug. She does not have to change.

CHAIR—That is if (a) Mrs Bloggs is prepared to pay more or (b) if they got—

Mr O'Sullivan—She only has to pay the therapeutic premium if a sponsor applies for that therapeutic premium and, if she does not want to pay it and she wants to stay on the drug, the doctor can simply apply for an exemption.

Senator FIERRAVANTI-WELLS—I know, but there is also the question of the interchangeability. There is a ratio of three to one. Mr Miles went through that with us this morning. You cannot interchange Lipitor, and we went through that process—

Mr O'Sullivan—But the government pays for an outcome; it does not pay for a drug, and the outcome should cost the same—

Senator FIERRAVANTI-WELLS—I know that.

Mr O'Sullivan—That mechanism is a good way of ensuring that the government pays the same price for the same outcome.

Senator FIERRAVANTI-WELLS—I appreciate that, but at a time the government makes the decision the minister does not know down the track. The minister assumes that there may not be a price differentiation, but the reality is that there could be a price differentiation—

Ms Riley—That is absolutely correct.

Senator FIERRAVANTI-WELLS—and that is really what it gets to. The decision in this case appears to have been made purely in a budgetary context without reference to the potential repercussions in the market that the government's intervention may have in terms of price, patient reaction and the actual effect on patients of that interchangeability. That is the point that I am trying to make.

Senator RYAN—There is something that I want to clarify, Mr O'Sullivan. When companies apply for TGPs they are usually, if not in almost all cases, in response to a price cut offered to the company by the government as a result of the calculations involved in the TGP process. When you are grouping together different molecules in the therapeutic group process and you

find therapeutic group premium is being applied that is usually in response to the price falling within that therapeutic group, is it not?

Mr O'Sullivan—It could be, yes.

Senator RYAN—I do not know of many examples where those TGPs have been applied other than in response to a fall in the price paid for by the government for the outcome. In effect, if a company wishes to maintain its price, a TGP is applied so the patient pays the premium if they need to as a result of a government price cut not as a result of someone saying, 'I want to put an extra three or four dollars on the product.' Isn't that correct?

Mr O'Sullivan—It could be both.

Senator RYAN—But it is usually in response to a calculation that lowers the price within a therapeutic group, is it not?

Ms Riley—Yes.

Senator RYAN—I think that is an important point outlined here, Senator Fierravanti-Wells. With the announcement of these particular therapeutic groups last year we went into a slightly new space. As I understand it, most therapeutic groups now contain at least one off-patent molecule other than the ones announced last year. Is that the case?

Ms Riley—Probably yes.

Senator RYAN—They go back 10 years. We would be looking at substantial patent expiries—

Ms Riley—I cannot think of one that is not—

Mr O'Sullivan—For example, both the statins are on patent at the present.

Senator RYAN—That was announced last year. If we put those to one side—

Ms Riley—The previous ones—

Senator RYAN—Which I believe are R2, RAs. This is slightly different, because we are grouping together with the new high-potency statins two patented medications.

Mr O'Sullivan—Yes.

Senator RYAN—I think that is an important point here, because the other therapeutic groups all contain off-patent medications which, since the introduction of the F1 and F2 formularies, have an element of competition. Even before those two formulas were applied you still had off-patent medications in those therapeutic groups. From a pharmacist's point of view, Ms Riley—and putting aside the points made by AstraZeneca earlier to use rosuvastatin and atorvastatin—I assume you would not like to see patients coming in and changing from one product to the other every six months.

Ms Riley—No, not at all. It is not good practice. It is not good therapeutic practice at all. And, as has been alluded to, it adds to confusion, it adds to decreasing compliance, it adds to a lot of things. So from a pharmacist's perspective, yes, unless there was a good therapeutic reason to be changing. Just because one is cheaper than the other is not necessarily the best therapeutic reason to be changing it.

Senator RYAN—I suppose that is one of the nubs of this. What does interchangeability at the patient level mean when the data is all based on population level submissions to the PBAC? Finally, I understand you mentioned in your submission the ability of a medical practitioner to ring up Medicare Australia and get an authority to remove the therapeutic group premium, but not any brand price premium. In your pharmacy, would it be fair to say that most of the authority prescriptions you saw were for listings on the PBS that were authority-required listings, as opposed to authorities to waive a therapeutic group premium?

Ms Riley—Absolutely.

Senator RYAN—There are not many TGP authorities waiving the therapeutic group premium, are there?

Ms Riley—Not many, no. Quite frankly and honestly, if you advocate for the patient and ring the doctor up and suggest that this could be done, it does not usually achieve a positive outcome.

Senator RYAN—I appreciate you cannot speak on behalf of doctors, but you all have some experience working with them. You mentioned earlier there was some confusion amongst medical practitioners about whether they could apply for waivers of premiums, and there is always confusion between therapeutic group premiums and brand priced premiums. Is that because of a lack of information? Is it resistance? Is it because it is a complex process? Is it the time taken? Or is it a combination of those—that we see a resistance from medical practitioners to accessing that particular option?

Ms Riley—I think it is a combination of things. Everybody is busy. Everybody gets lots of mail, and we get lots of mail from Medicare Australia about these kinds of things and the doctors get the same kind of mail. Sometimes it is not easy to understand. So I suspect the complexity of the explanation is sometimes very difficult. It is a combination of things. I do not think it is a lack of willingness, put it that way.

Senator RYAN—Sure.

Senator MOORE—I was interested in the same point, regarding evidence that doctors are confused when prescribing medication, which I found deeply concerning. I know we have been trying over the years to make the pharmacists and the doctors work more closely together so that processing is a cooperative arrangement. I will check later with the PBAC and the department about the kind of information that has gone out, as you have talked about, regarding the various ways that people can work with the system. It is always difficult. Did you get the piece of paper that was handed out about the drug companies?

Dr Tatchell—No.

Ms Riley—We do not have that, no.

Senator MOORE—If a medication is changed because a doctor is concerned that the price could be difficult for his patient, the format of the medication is currently under prescriptions. Could we get something on notice from you regarding the process of working out an arrangement? I know it is difficult.

Ms Riley—Yes, sure.

Senator MOORE—That is a very complex explanation of people having to cut tablets and things—

Mr O'Sullivan—I think in the real world this does not happen. A doctor will read the product information when prescribing either rosuvastatin or atorvastatin. They will not read the public summary document to check that the dose relativity is three to one. That is something used in the WAMTC process to make sure the outcomes we receive—

Senator MOORE—I have been with patients and it has been an ongoing concern of this government and previous governments about security of medication and about working with people who are taking complex medications. The aspect of having two prescriptions and having to cut up tablets and things like that—

Mr O'Sullivan—I have never dispensed a prescription like that.

Senator MOORE—is that something from the Pharmacy Guild's perspective?

Mr O'Sullivan—No.

Ms Riley—No, I have never dispensed a prescription for taking half an atorvastatin tablet, quite frankly.

Senator MOORE—You could, though?

Ms Riley—I do not know if you are familiar with what the tablets look like, but the reality is that—

Senator MOORE—No, we did not get to see the samples. That was really upsetting!

Ms Riley—Well I am pleased to know you do not need to take them. The reality is that they are an oval shaped tablet without a score in the middle.

Senator MOORE—So you could not cut them?

Ms Riley—They would not be cut very practically and not very safely, I would expect.

Mr O'Sullivan—Ringing up and getting an authority to waive the TGP would be a lot easier, believe me.

Ms Riley—It would be a lot more sensible.

Mr O'Sullivan—That is what the doctor would do.

Senator MOORE—It gets back to the doctors' understanding that they can do that and knowing how to do it.

Mr O'Sullivan—The doctors can receive a statement and, until it is done, they can keep their patient on the medicine they decide is best for that particular patient. If the patient does not want to pay the TGP, they can be waived.

Senator MOORE—Certainly, so much of the discussion has been on cost. For a situation like this, because we are using it as a case study, within the proposed therapeutic group—and my understanding is that this particular therapeutic group has not started yet—

Ms Riley—No.

Senator MOORE—No-one has actually said that on record. If this group came in and it was there, could you give us some idea of the difference in cost? We have been talking about—

Ms Riley—Whose cost—the patient's cost or the cost for the government?

Senator MOORE—The patient's cost. We have been talking so much about the impact on the patient, understandably, to ensure that people do not have undue costs in their budget. Regarding the range of medication and the impact of the cost, I am trying to quantify—

Mr O'Sullivan—Unless there is a TGP applied by a sponsor, the patient will pay $5.40 if they are on a concession.

Senator MOORE—And it could go upwards if—

Mr O'Sullivan—If a TGP is applied, which they do not have to pay if they do not want to.

CHAIR—Is there likely to be a TGP applied?

Ms Riley—That is the sponsor's decision. We do not know at this stage of the game where they are going to go with that.

CHAIR—In this case, is it usual is that a TGP is applied?

Mr O'Sullivan—In the Department of Health and Ageing submission, it says it is vary rare.

Senator MOORE—I will ask them about that as well. In the therapeutic groups that are in place now—the ones prior to the bunch that were proposed last year—have these issues come up?

Mr O'Sullivan—In my experience they have never been a big problem.

Senator MOORE—From the point of view of giving out the medication?

Mr O'Sullivan—Of patient access.

Senator MOORE—Of course, you cannot speak for everybody, but in terms of the kinds of concerns we have heard raised about this impact of cost, the experience you have had with the previous groups, allowing that they are different medications and all those things, what could happen has not been to the monumental level that we have been hearing about.

Ms Riley—No. Given that the previous groups are significantly genericised now, there are opportunities as well. You cannot get away from the fact that cost is an issue for consumers. These are all medicines for chronic conditions. People are not just taking one; they are taking loads of other medicines for loads of other conditions. It is just adding up the bill. That is the problem. If one tablet needs to go to two tablets, it means two prescriptions a month, and that is twice the cost. That is perfectly obvious. From the patient's perspective, if the doctor, for whatever reason, changes the medicine and they already have a packet of those tablets, what does the patient do? Do they continue taking that packet until it is finished, which is probably what happens, and then start their new medicines, or do they stop in the middle, or do they take both? They are the things that really concern me as a practising pharmacist. We have to get those messages across to patients. You have to think about cost, but you have to really hone in on the fact that you must take the right medicine—the one that the doctor wants you to take and the one that you have agreed with the doctor that you will take. The big concerns are about chopping and changing medicines. There is an opportunity for people to either double up or take the wrong one for a period of time. That is a big problem.

Senator MOORE—In terms of safety of medication.

Mr O'Sullivan—There is the safety net scheme, which has a limit to the amount of co-payments the patient has to pay.

CHAIR—I have one clarification. You said at the beginning that you do not oppose TGs; it is the process and making sure that the health outcomes are achieved and that it is transparent.

Ms Riley—Absolutely.

CHAIR—I just wanted to get that clear. It seems that significant work needs to be done on the process.

Ms Riley—The intent of the policy is good, but the reality is we are not sure what goes on underneath that. That is where we have our concerns.

CHAIR—You referred to the previous group of TGs being genericised—

Senator MOORE—Another new verb!

CHAIR—Yes. The groups that are proposed now have not gone through because they were disallowed, but what is the degree of genericisation? That is another new word!

Ms Riley—We need a new dictionary today!

Mr O'Sullivan—We would have to take that on notice.

CHAIR—That would be appreciated if you could take it on notice. But it is not just the point of swapping a generic, it is the interchangeability of it across different medicines.

Ms Riley—We have got two problems. There is the generic issue and then you have got the interchangeability issue from medicine A to medicine B.

CHAIR—Thank you very much for your time. It is appreciated.

[11.30 am]

LYNCH, Ms Katharine (Kate), Chief Executive Officer, Generic Medicines Industry Association

CHAIR—Welcome. Is there anything you want to say about your appearance here today?

Ms Lynch—I am also known as Katharine Watson.

CHAIR—I want to check that you have in fact been given information on parliamentary privilege and the protection of witnesses and evidence.

Ms Lynch—Yes.

CHAIR—We have your statement, so now you can go for it making an opening statement, and then we will ask you some questions.

Ms Lynch—Many thanks for the opportunity to make a statement this morning. The Generic Medicines Industry Association is a national association representing companies that manufacture, supply and export generic medicines, being those medicines that are not protected by valid patents applied by those sponsors who have not originally held the patent for that medicine. The members of GMIA supply more than 90 per cent of total prescriptions supplied by generic sponsors in Australia, making the association highly representative of the sector. The members of GMIA sold more than 50 million services, or 33 per cent of all services by volume, on the PBS over 2008-09. The members of GMIA sold 100 million packs in total in Australia over 2008-09. The members of GMIA employ 5,000 Australians, with almost half these roles being in manufacturing or research and development roles, functions that generate strong economic multiplier benefits. Members of GMIA export $470 million worth of product, which represents approximately 12 per cent of the current pharmaceuticals export market.

The generic medicines sector is strategically an important industry sector. The sector contributes to economic growth through the creation of high skill jobs and exports. A sound medicines-manufacturing base brings important public health benefits in times of pandemic or other urgent need. Generic medicines provide patients access to effective, high-quality medicines at more affordable prices by introducing competition after the monopoly period enjoyed by the originator sponsor has expired. The presence of competition from generic medicines provides a stimulant to further drug discovery and innovation more generally. Extended or permanent monopolies on pharmaceutical products remove the incentives to discover new medicines.

I would now like to turn to the terms of reference before this committee and handle each term of reference in turn, starting with reference term (a). The impact of therapeutic groups to consumer access will be negligible. In many instances there will be no change to the price faced by the consumer. In the small number of instances where a patient premium is imposed, many patients can be successfully switched or obtain an exemption from the premium on medical grounds. Therapeutic groups policy is consistent with evidence-based funding of medicines, a philosophy that is central to the PBS and enshrined in the National Health Act. Innovation is

rewarded in an evidence-based system by awarding price premiums to products that can demonstrate the delivery of improved health outcomes. Therapeutic groups only apply to medicines that have a similar therapeutic significance, that is, medicines that cannot demonstrate the delivery of an improved health outcome. Therapeutic groups are a policy tool that allows the government to ensure that products of similar therapeutic significance are priced at the same level. Responsible price setting of patented medicines is crucial to the sustainability of the PBS. The share of PBS receipts to the F1 formulary has increased by 35 per cent over the last four financial years. It is the patented products that will continue to drive future growth of PBS expenditure. Any suggestion that Australia's public budget should be accommodating increasing costs of research and development are ill-founded. The restraint of costs on patented medicines that do not demonstrate a therapeutic significance is responsible policy-making.

Turning to reference term (b), substitution of a different brand of the same medicine by the pharmacist with consent by the patient was introduced in Australia on 1 December 1994. To make that clear, this refers to the generic medicines, not to the therapeutic groups instance. This policy of substitution of generic brands has provided significant benefits to the Australian public by making medicines more affordable and has shown that substitution of different brands of medicines can be rolled out successfully in Australia.

The existing market mechanisms currently overseeing the introduction of therapeutic groups can be achieved successfully in Australia with the oversight of patients by expert and tailored medical care delivered by physicians, with the ability to obtain exemptions to the patient premium on medical grounds and, thirdly, with appropriate expert advice in defining the medicines that should sit within the therapeutic groups. With these three factors in place, patient health outcomes can be such that they would not be jeopardised and the important policy benefits that come with therapeutic groups would be achieved.

Turning to reference term (c), varying the size of patient contributions can be important, contributing strongly to good medicines policy. Consumers should be rewarded financially, encouraged and empowered to make fully informed and wise medicine choices. Variable patient contributions provide a market mechanism to financially reward consumers who make wise medicine choices. The Generic Medicines Industry Association requests that the committee recommend the introduction of a lower patient co-payment for those patients who choose a generic medicine, so that patients who choose generic medicines are rewarded directly for that wise choice.

Reference term (d): the GMIA supports the concept of therapeutic groups and is confident that the development of new therapeutic groups can be made successfully in the context of appropriate expert advice in defining the therapeutic groups, with appropriate understanding being given to physicians so they can appropriately advise their patients, and with appropriately defined medical exemptions where patients for whom it is not suitable to switch a medicine may be exempted from the therapeutic group premium, if one is so imposed.

Reference term (e): the Australian government has traditionally and appropriately stated that the government pays for health outcomes delivered by the medicines listed on the PBS. This is important, as it ensures that funding of a socially subsidised scheme such as the PBS is targeted to health outcomes and ensures that sponsors of medicines are incentivised to develop and commercialise medicines that deliver improved health outcomes. The classification of medicines

into the F1 and F2 formularies weakens the government's ability to ensure that prices on the PBS reflect the same health outcomes delivered.

Reference term (f): the delay to price reductions associated with the price disclosure provisions reflects the fact that the price disclosure policy is poor policy. Price disclosure is incompatible with the principle of equal government subsidy for equal health outcome. The price disclosure policy process itself places considerable administrative burden on both sponsors and the government. Cost and time resources associated with the collection and analysis of data to support price disclosure policy are significant. To date, the policy only affects 19 molecules. If contemplated proposals by government role out, the number of molecules captured by price disclosure will increase in number, making it even more administratively burdensome.

Price disclosure policy is conceptually complex. The risk of inadvertent error by both sponsor and government is high and there is limited capacity in the system to identify these errors. Further, the weighted average disclosed price calculations are complex and, due to the commercial-in-confidence nature of the input data, weighted average disclosed price calculations are necessarily non-transparent. The process creates uncertainty for the government and also for the sponsor, on the cost to the PBS overall and future price levels. Results to date emphasise the unpredictability and variability of price reductions, where two-thirds of the 19 products that have to date been subject to price disclosure have resulted in no price adjustment and, of the remaining one-third of products that were subject to a price reduction, these varied considerably, ranging from 15 per cent to 71 per cent. Price disclosure fails basic tests of efficient regulation, creating high compliance costs and uncertain and unpredictable market conditions. GMIA requests that the committee recommends that the price disclosure policy be abandoned.

Reference term (g): GMIA supports timely market access of new medicines to the PBS and requests that the committee recommends the introduction of monthly entry of new generic medicines onto the PBS to realise important savings to the PBS and to replace the current situation where a new generic medicine can be delayed for up to four months before being able to enter the PBS.

Reference term (h)—any other related matters: GMIA notes that one of the key consequences of PBS reform is the reduction of prices of generic medicines. Generic medicines play a crucial role in the delivery of affordable medicines to the Australian public after the market exclusivity of medicines has expired. The PBS underwent major reform in 2007, which was forecasted at the time to save the government an estimated $3 billion over 10 years. Just two years into these reforms, three independent analyses have projected that the savings would be around double this—in the vicinity of $6 billion. The 2007 reforms have already begun to have a deleterious impact on the pharmaceutical industry in Australia, with significant job losses. Manufacturing and R&D facility closures will come next. Any further reform before the major 2007 reforms have played out will severely damage Australia's leading export industry in transformed goods.

GMIA requests that the committee recommends that there be no further reforms to the PPS as reforms from 2007 have yet to play out and will deliver significant savings to the government. GMIA requests that the committee recommends that the government put in place a floor price of $5 for low priced pharmaceuticals to ensure the ongoing supply of essential medicines that have a low ex-manufacture price. GMIA requests that the committee recommends that the government amends the Patents Act to allow the manufacture of generic medicines for export,

which is currently prohibited under domestic legislation, and recommends that the committee recommends that the government expressly authorises sponsors of generic products to copy the product information and other related documents from the originator's regulatory documents by means of amendment to the Copyright Act for the purpose of obtaining market approval from the Therapeutic Goods Administration and for the purpose of sale and marketing of the product in the Australian market. This will ensure that sponsors of generic medicines can continue to supply generic medicines to the Australian public.

Senator FIERRAVANTI-WELLS—I get the distinct impression from looking at your submission that this is really about your concerns with the PBS reforms rather than specifically dealing with the matter at hand, which is the benefit or otherwise of therapeutic groups. Was the generic medicines industry in favour of the PBS reforms?

Ms Lynch—The generic medicines industry has not been consulted on the PBS reforms.

Senator FIERRAVANTI-WELLS—Was your association in existence then?

Ms Lynch—Yes, our association has been in existence since 2001.

Senator FIERRAVANTI-WELLS—Obviously you believe that there are some concerns with the PBS system as it currently operates.

Ms Lynch—Our association has serious concerns about the PBS reforms. The consideration of the therapeutic groups is pivotal to the sustainability of the PBS. It is important to consider the entire sustainability of the PBS when considering one aspect—the therapeutic goods policy.

Senator FIERRAVANTI-WELLS—So, potentially, you see the use of therapeutic goods as a way of effectively not dismantling but eroding some of the PBS reforms?

Ms Lynch—The therapeutic groups build on the fundamental principles of the PBS, which is about rewarding health outcomes. Taking it from that basic principle, we therefore support the therapeutic groups. Patented medicines will be the key driver of PBS growth in the future and therapeutic groups provide the government with one policy tool to ensure that the patented medicines on the PBS that do not offer therapeutic significance in terms of better health outcomes are not inappropriately rewarded with an overly high price.

Senator FIERRAVANTI-WELLS—In your recommendations, you propose that the originator brands have an additional $5 out-of-pocket cost to the patient. What are the patient health benefits of your proposed pricing?

Ms Lynch—The ongoing viability of a sustainable generic medicines sector is reliant upon the use of generic medicines. By definition, at day zero of market entry of a generic medicine, there is zero market share for that medicine. Entire market share is with the originator brand. It is critical to the sustainability of the generic medicines sector that there be some incentive to encourage patients to move from the originator brand to the generic medicine. International studies have shown that the most effective trigger to switch patients from an originator brand to a generic brand is a clear financial price signal.

Senator FIERRAVANTI-WELLS—It is clear from some of the submissions that not all patients can switch to a generic medicine. Does your proposal allow for such a patient to be exempt from paying the extra $5?

Ms Lynch—Let me answer that in two ways. In the first instance, the term 'therapeutic groups' applies to medicines that are therapeutically similar. The proposal that we are discussing currently applies to medicines that have been shown to be bioequivalent and since 1994 they have been accepted by the Australian community to be substituted by the pharmacist. The decision to switch to the therapeutic groups would be made at the physician level. For generic medicine, the decision is made at the pharmacy level.

Senator FIERRAVANTI-WELLS—What you are really saying is that generic medicines should be given an artificial floor price below which they cannot fall. At the same time, it is also suggested that your competitors have an additional $5 over and above your products so that you can enjoy an ongoing competitive advantage. That is the gist of what you are saying. It is to financially benefit the generic medicines industry and to give them an ongoing competitive advantage solely to support the generic medicines industry.

Ms Lynch—The two policy proposals—the $5 patient copayment and the $5 floor price—seek to meet very different policy objectives. The patient premium seeks to provide the patient incentive to move from the originator brand. By definition, at market entry of the generic medicine, the originator brand will have 100 per cent of the market. There is no incentive for the patient to switch brands, and without a switch there is no generic medicines sector. There is not a level playing field between a generic brand and an originator brand because they already have market share. So there needs to be a policy incentive to 'level up' the playing field so that the generic medicines can have an objective to—

Senator FIERRAVANTI-WELLS—Assuming that your plan to give you a $5 advantage goes ahead, what is that worth to your member companies? You are really asking to be subsidised and to effectively price out competitors and give you a $5 advantage.

Ms Lynch—The concept of sending a price signal to the patient is well established in other jurisdictions. The sponsor of the originator medicine is also able to compete on a generic market level footing as they are also able to register a new brand under a different brand name. So the objective of the policy would be to achieve a full switch from the originator brand, which has had many, many years to develop brand loyalty to its brand name, and ensure that all patients are on a genericised or new brand of that particular molecule. The originator sponsor is able to participate in that market by means of launching a new brand, and they typically do that already in some instances by launching a new brand.

Senator FIERRAVANTI-WELLS—So what do you say is the additional cost to the PBS? Have you done any economic modelling on that? You can take that on notice, if you have, and—

Ms Lynch—I can answer it in principle. We would recommend that the additional patient co-payment be set such that it is budget neutral. We would expect that very few patients would pay that additional premium. We would then have a situation where all patients are on a generic brand including any potential brand that an originator sponsor may wish to launch, and all sponsors are then playing on a level playing field.

Senator FIERRAVANTI-WELLS—I understand that under the previous government about $20 million was allocated to assist the generic medicines industry and I understand that that budget allocation under this government has been cut to $4.3 million. Is that the case?

Ms Lynch—That is correct.

Senator FIERRAVANTI-WELLS—In other words now the viability of the generic medicines industry is well and truly in question and this is perhaps a suggested way that the generic medicine industry could continue with some degree of viability?

Ms Lynch—Further education and market knowledge of the benefits, quality, safety and effectiveness of generic medicines is always welcomed. When we look at the experience in other international markets of encouraging switch to generic medicine our members would suggest that that is one of the less effective ways.

Senator RYAN—From your submission I take it that you would like to see higher generic utilisation where there are generics and originator medicines in the market.

Ms Lynch—Correct.

Senator RYAN—Do you also want to see lower prices for generics?

Ms Lynch—Absolutely. The presence of a generic medicine and a viable generic medicine sector and the entry of generic medicines into the market are about making medicines more affordable. As the volumes and usage of generic medicines increase, the ability to make medicines more affordable increases.

Senator RYAN—I appreciate that and I understand the view that there is substantial room to bring Australian generic prices down to international levels, because for a number of areas we still pay more than other nations with national insurance schemes or the like. But do I take also from your submission and from your verbal comments that you do not support the PBS reforms with the F1 and the F2 formularies, essentially because they break down the old reference pricing system between genericised molecules and patent protected molecules. Do you want to see a reinstatement of the old reference pricing system? You have not said so but that is what I am gathering from your submission and from what you have said in your presentation.

Ms Lynch—Yes. We think that the delinking of the F1 and F2 formularies is erroneous because it moves away from something that has long been enshrined in the PBS, that the reward of health outcomes is reflected in the price.

If I may pick up on an assumption that you made, that the prices of generics are high in Australia by international standards, we disagree with that. I think that international price comparison across any commodity is fraught with difficulties and this is no more so than with pharmaceuticals. For every medicine that we can see there are just as many medicines that are priced more highly in generic sectors versus other markets. There will be just as many priced lower.

Senator RYAN—Isn't it true—and I am happy to be corrected as my knowledge might be a few months out of date and I know the gap has been narrowing—that on substantial volume medicines such as simvastatin, which I understand is now off patent in most parts of the world, Australians were paying through the PBS a higher price than that that was available through the British NHS or through Walmart in the US if I walked in there with a prescription?

Ms Lynch—Simvastatin is an often cited molecule in terms of international price comparisons. I reiterate a very clear warning about honing in on single molecules. It is important to look at the whole formulary.

Senator RYAN—But it is a pretty big molecule.

Ms Lynch—I would also add that in the UK simvastatin is used on the first line. Any patient that has elevated cholesterol—

Senator RYAN—We are pressed for time, Ms Lynch.

Ms Lynch—We need to look at the entire market dynamic there.

Senator RYAN—Okay.

Ms Lynch—As for the clinical use of simvastatin, it is very different in Australia from that in the UK.

Senator RYAN—Okay, but it is a product with a similar scale in a lot of markets. It was a popular cholesterol-lowering medication.

Ms Lynch—It was. It no longer has the volumes in Australia as it does—

Senator RYAN—It no longer has its market-leading position. I appreciate that. I strikes me though that I am not quite on top of the argument as to why your organisation is opposed to the price disclosure regime.

Senator MOORE—That was my question, Senator Ryan, so, yes, if we could get some more information about that. Ms Lynch, you spend a lot of time in your submission and in your opening statement on that issue, which no-one else has raised to that extent—so if we could get more information.

Senator RYAN—I will ask and you can chime in if you wish.

Senator MOORE—No, that is it. That is the question about your focus on the price reduction.

CHAIR—I was going to ask it too. Maybe we could spend the remaining couple of minutes on that.

Senator RYAN—Sure. If I may, I will ask a couple of very brief questions before I get to that.

CHAIR—Very brief!

Senator MOORE—We all liked the last one.

Senator RYAN—Ms Lynch, the point of a patent is that there is a monopoly for a period of time on producing it. That is the whole point, that we have a patent system that applies—

Ms Lynch—The point of the patent is to give the market exclusivity. No other supplier can provide that molecule.

Senator RYAN—That is true where we have patents everywhere.

Ms Lynch—Yes. There is not attached to that a right to command a particular price.

Senator RYAN—The right to command a price is in the hands of the buyer.

Ms Lynch—The technology must deliver a better outcome.

Senator RYAN—I appreciate that. But it is basically a patent, so only I can produce it until my patent expires, whether that be over intellectual property in other areas or over a medicine or over something else. So of course I have a monopoly position until that patent expires. This is where I want to go into the disclosure regime. One of the things that you mentioned is the administrative burden. I appreciate the administrative burden and I think that everyone accepts that with regard to the PBS it is not administratively easy for a lot of people, so I accept that point. You refer to 'uncertainty for the sponsor over future price levels' and 'the unpredictability and variability of price reductions'. Isn't that the point of actual genericised competition, that we have uncertainty because it has become a commodity: you can produce it, I can produce it and other companies can produce it. Isn't that the point of not having a limitless patent on a medicine, so that there is competition? One of the ways by which we could have a price signal to consumers—and I know this has happened in the past—is by a generic company saying, 'We're going to offer a price cut to put pricing pressure on a competitor,' whether that be another generic company or an originator company with its original brand. So I suppose there are two questions. Firstly, it seems to me that uncertainty is intrinsic to the idea of a genericised molecule. Secondly, we could have price signals and price pressure could be put on by competition in the marketplace.

Ms Lynch—What was the second part?

Senator RYAN—The second one was that we have got multiple generic companies that manufacture molecules, especially the larger molecules, or market them once they come off patent. Couldn't we have a price signal to consumers—and indeed to the government through the PBS—by some of these companies actually competing with one another and offering price reductions? To me that is the point of a commoditised molecule.

Ms Lynch—The basic assumption of price disclosure is that we have a fully functioning competitive market. Through the PBS and the pharmacist acting as the agent we do not have a properly functioning competitive market. The generic medicines market in Australia pretty much breaches all the basic assumptions that must be in place to have a fully functioning economic—

Senator RYAN—I appreciate that it is not a fully functioning market, but one company could offer a price cut.

Ms Lynch—All those outcomes that you are suggesting should be happening in a fully competitive market do not necessarily happen for a generic medicine.

Senator RYAN—A company that said, 'I want to get into this market for an expired molecule in a big way'—it was a large product, and I appreciate that it will happen on larger products more than on small ones—could actually say, 'We are going to offer more than the 12.5 per cent reduction,' which would then bring down the whole price that is paid for that molecule on every competitor. The price signal would happen that way, wouldn't it, through a brand price premium? That has happened before, I understand: some companies have offered price cuts in an attempt to get market share.

Ms Lynch—What we have seen since the introduction of PBS reforms in 2007 is very few manufacturers passing on the price reductions through brand price premiums and, instead, more fierce competition in the marketplace.

Senator RYAN—Surely, if the government is getting the benefit of the price cuts, that means to a certain extent the system is working. If I offer a price cut, you offer a price cut and a third or fourth company then matches it, doesn't the PBS and its long-term sustainability benefit from the fact that the price has fallen?

Ms Lynch—In the short term, the prices could fall; in the longer term, the commercial incentive to enter the market as a generic medicine is removed. So my prediction is that for some of the larger molecules that are coming off patent in the next few years we will see generic market entry of these medicines. In the worst-case scenario, they will come from international operations, with perhaps five Australian staff sending these medicines out with no patient support. They will be white-boxed, basic medicines sent out through a base of five Australian jobs. For the large number of molecules—

Senator RYAN—The PBS is not a job scheme; it is a health scheme, as you have said yourself. I am not particularly worried by where the medicines come from if they meet—

Ms Lynch—I think it is very narrow sighted not to consider where the medicines come from. I think there are other benefits, which I have talked about, in having a sound pharmaceutical manufacturing base in Australia, particularly in cases of pandemic or other urgent need. I also think that we will see those packets of very basic white pills come in for the large molecules, but other pieces like patent challenges and the market entry of the less profitable molecules, which in their cumulative cost to the PBS are quite substantial. They are the molecules that will not have generic competition, and substantial lost savings to the PBS will stem from those.

Senator FIERRAVANTI-WELLS—In your evidence you categorically stated that GMI was not consulted as part of the PBS process. I ask you to reflect on that answer. Ms Brown from my office, who was then senior adviser to Mr Abbott, advises me that GMI were part of the process and were consulted through your previous CEO, Di Ford. So perhaps you would like to reflect on your answer and, if you so choose, correct the record.

Ms Lynch—As you correctly point out, I was not personally present during that time. Members of my board who were there advised that there was no thorough consultation prior to the announcement of the PBS reforms. There was some consultation post the announcement in terms of how the detail of the reforms might be implemented, but I am very happy to take that on notice and make a fuller statement from those who were present.

Senator FIERRAVANTI-WELLS—Perhaps you would, because you have made some pretty categorical statements, and I would appreciate it if you could reflect and, if necessary, provide the necessary documentation to this committee as to your assertions.

Ms Lynch—Thank you for that opportunity to make a correct statement there.

CHAIR—It would be appreciated if you would clarify timing for the committee. You are a member of the community that has in the past made claims about being consulted, but there are different kinds of consultation. So perhaps you could outline what you mean so that we are really clear about what you mean by consultation.

Ms Lynch—I think that is a very important point and thank you for the opportunity to make it completely clear.

CHAIR—Thank you very much for your time and your evidence today.

[12.05 pm]

BENNETT, Ms Carol, Executive Director, Consumers Health Forum of Australia

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

CHAIR—I now welcome representatives of the Consumers Health Forum of Australia. I know you have both done this many times before and I understand you have been given information many times on parliamentary privilege and the protection of witnesses and evidence. We do have your submission. I invite either of you or both or you to make an opening statement and then we will ask you some questions.

Ms Bennett—Thank you. I appreciate the opportunity to present the views of Australia's peak national body representing health consumers on this very important issue. I would also like to thank you for your willingness to engage in this important process of reviewing PBS policy. It is an issue that is very important to Australia's health consumers.

On that note, I would like to begin by emphasising the value of the Pharmaceutical Benefits Scheme to health consumers. The Consumers Health Forum has been in operation for more than 22 years and medicines policy, including PBS policy, has been a bread-and-butter issue for us throughout that time. CHF is supportive of the National Medicines Policy and its four objectives—the timely access to medicines that Australians need at a cost that individuals and the community can afford, medicines meeting appropriate standards of quality, safety and efficacy, quality use of medicines and maintaining a responsible and viable medicines industry. The PBS works to ensure that these objectives are met. CHF believes it is essential that the PBS remains viable into the future and supports PBS reform that allows for its continuing sustainability.

Australia has managed to keep medicines access high while costs remain comparatively low in spite of the small size of this market. We are the envy of the world due to our ability to maintain the low cost of and high access to pharmaceuticals through the PBS. We acknowledge the costs of the PBS have grown at an average of 10 per cent in the last decade and the need to find ways to ensure this sustainability is important as long as there is no major detriment to consumers. We also acknowledge that the viability of the industry is a consideration in order that Australian consumers have continued access to quality medicines.

CHF members have consistently championed the PBS as a key component in supporting them to maintain their health. This is particularly important for consumers with long-term and chronic conditions. In relation to the latest PBS reforms, CHF has consulted with consumers, who reported no major detriment overall. CHF argues that consumers will experience a major benefit from the reforms due to the PBS's ongoing viability. For any PBS reform, CHF considers that there are several tests that must be applied. Consumers must not be disadvantaged, whether in access, cost or safety and quality. When the PBS reform was announced in November 2006, the Minister for Health and Ageing stated that consumers would not be disadvantaged by the reform. While CHF has not received any indication from our members overall that they have been disadvantaged by the PBS reforms that we are talking about today, we are aware that there are

particular groups that have concerns about interchangeability in therapeutic groups and it is important that the impact on consumers continues to be monitored.

We would like to specifically highlight two aspects of the new reforms in our evidence—the therapeutic groups and the cabinet approvals. In terms of therapeutic groups, CHF is, on the whole, not opposed to this policy and does not believe that overall this policy has disadvantaged the majority of consumers. Consumers acknowledge that new therapeutic groups should not reduce access to necessary medicines, including high-cost medicines, as there are mechanisms in place to allow consumers to access any medicine in a group at the base price as long as it is requested by the prescriber. We would argue that these safeguards are an essential component of this policy in ensuring access by containing costs for consumers. As the senators on this committee would well know, out-of-pocket costs for consumers, particularly those with chronic conditions who are met with a range of costs, is a big issue.

Our consultations with consumers clearly indicate that consumers are faced with a choice about whether to forgo essential medicines when they are struggling to pay food, heating and other essential costs of living. Consumers and health professionals should be informed about exemptions from therapeutic group premiums where higher cost drugs are required and it is important that exemptions are applied for consumers who need, but would otherwise suffer from a decision to use, a higher cost drug.

Medicines within therapeutic groups must be interchangeable. CHF believes that clinical effectiveness must be the basis on which these decisions are made and they should be rigorous and transparent. While we are satisfied that the Pharmaceutical Benefits Advisory Committee is the appropriate body to provide this assurance in its role in advising on therapeutic groups, therapeutic groups are not subject to public consultation and transparency, something we heard a lot about this morning from the consumer groups. The criteria upon which clinical evidence is based by the PBAC are unclear. Transparency must occur if public confidence is to be maintained in claims of therapeutic equivalence of medicines within a particular group. Where there are significant concerns about interchangeability, therapeutic groups should not be formed. CHF is aware of the concerns that have been raised in relation to the interchangeability of some new therapeutic groups, particularly the oral bisphosphonates, selective serotonin reuptake inhibitors and of course the anti-epileptic group of drugs, which are also a concern for consumers although they are not a therapeutic group.

CHF argues that stakeholder consultation, including consumer consultation, is required in the formation of therapeutic groups to ensure that the relevant benefits and potential disadvantages are considered. Consumers are the people who are living with their medications on a daily basis and will suffer the most if they are switched to an inappropriate medicine that is not interchangeable. Their experiences must be taken into account in the assessment of interchangeability. Where CHF has undertaken consultation for the PBAC on the listing of particular drugs on the PBS through the development of consumer impact statements, this has been really valuable. Consultation must also be proactive in order to bring these important decisions to the attention of consumer groups, who are often under-resourced not-for-profit organisations without the capacity to monitor and assess the impact of emerging policies on the people that they represent.

In terms of the cabinet approvals process, CHF has identified that we would like to see greater transparency about the priority and time frames that are assigned to their consideration. Consumers should not be unduly disadvantaged by lengthy cabinet approvals. We have seen that in relation to the PNH group and bone marrow disease, where there have been quite significant time delays in cabinet approval. Clinical effectiveness must be the basis on which these decisions are made and consumers have expressed some scepticism about whether that is the case. Where a conflict exists between timely access and gathering of evidence on which to base clinical effectiveness, clinical evidence should take precedence to ensure an informed decision that will protect consumers' safety. CHF notes the proposal in a number of other stakeholders' submissions that the threshold for cabinet approvals be increased from $10 million to $20 million. CHF would not be opposed to this increase, particularly where it would expedite access to necessary medicines.

In conclusion, CHF supports PBS reform as a way of ensuring the future viability of the PBS provided that there are no major negative impacts on consumers in terms of access, safety and cost. We also recognise that the viability of the industry and its capacity to continue to deliver quality medicines to the Australian market is a factor that must be taken into account in this policy initiative. CHF overall supports the reforms to the PBS. It is important that the criteria and evidence for clinical effectiveness for selection of therapeutic groups is transparent. Any major concerns raised by consumer groups about interchangeability should be taken into consideration of the ongoing viability of a particular therapeutic group.

Timely access is desirable but consumer safety is absolutely paramount and must take precedence over other considerations for cabinet approvals. Where possible, transparency about decision making and time frames should be available to the public. Consumers, as the payers and users of the PBS, must be involved in the process of decision making about therapeutic groups, and mechanisms to ensure consultation should be a fundamental part of this policy. I thank you for your time today, senators, and we look forward to the outcomes of this inquiry.

Senator FIERRAVANTI-WELLS—You were present this morning and you heard the exchanges that I had with various people about the definition of 'interchangeability'. Would you like to expand on what you see is an appropriate definition of 'interchangeability' and the sorts of processes you would like to see put in place.

Ms Bennett—We are not experts on what is interchangeable in terms of the clinical and therapeutic nature of medications. The Pharmaceutical Benefits Advisory Committee is the body that does provide advice about the clinical effectiveness of drugs for the listing on the PBS. The difference with this therapeutic groups policy is that the process for listing other drugs is a little more transparent in terms of the criteria that are used for looking at clinical effectiveness and in terms of the kind of evidence that is used by the PBAC to assess that effectiveness. With therapeutic groups that has not been the case. I suppose what we are really asking for is greater transparency about what the criteria are and what the basis of the evidence is for making those decisions.

Senator FIERRAVANTI-WELLS—In previous evidence one company talked about the 30,000 pages of material that are submitted for the listing of a drug. Does part of that process include consultation with organisations such as yours?

Ms Bennett—Not necessarily. In terms of the companies consulting with consumer groups?

Senator FIERRAVANTI-WELLS—No, in terms of the listing of drugs.

Ms Bennett—In terms of the listing of drugs, the agenda for the Pharmaceutical Benefits Advisory Committee is placed on their website six weeks before meetings and there is an opportunity at that stage for consultation with consumers; however, there has not been a capacity for that consultation to be very thorough. It is not always possible, as I said, for small not-for-profits to be proactive and to be monitoring the websites of all of the different health bodies that are making decisions in order to be able to provide good, rigorous consultative evidence to those processes. I think that is a really detrimental factor that could be improved.

Senator FIERRAVANTI-WELLS—Just on a practical level, we talked about the changes to transparency. You might like to take this on notice: do you have suggestions for how practically that process could be altered? I would appreciate your comments in relation to that.

You talked about the cabinet approval and priority. Indeed, the figures do stack up in terms of the length of time. The time between PBAC approval and cabinet consideration has doubled in recent years. Indeed, the figures show that the number of medicines costing over $10 million that were listed on the PBS between 2006 and 2009 actually halved. Obviously, there is a consumer concern from that perspective. It is taking twice the time to get half the number of medicines in the system.

Ms Bennett—Yes, and that is why we would support a review of the threshold and an increase in that threshold where it would enable more timely access to medicines and their consideration.

Senator FIERRAVANTI-WELLS—From your perspective, you do not know why it is taking twice as long to consider half as much?

Ms Bennett—No, we do not. I imagine it is because there are other priorities on the cabinet agenda. I guess greater transparency about the priority that is allocated to the decision making around drugs that consumers are relying on getting access to would be really useful. Short of that, if there is another way of providing more timely consideration of those approvals then we would support that.

Senator FIERRAVANTI-WELLS—One suggestion that has been made is that if everyone knew the criteria in terms of both the PBAC determining therapeutic goods or other processes then it would be easier to address those before you went through that process rather than later.

There was evidence given earlier by an organisation about the whole issue of the $10 million to $20 million, which you have raised as well. Did you seek any assurances and did you receive any assurances before the last federal election from the then opposition spokeswoman or anyone else now in government about revising or reviewing that $10 million to $20 million threshold?

Ms Bennett—I was not in this role at that point, so I cannot comment on the organisation—

Senator FIERRAVANTI-WELLS—You might like to take that on notice.

Ms Bennett—Yes.

Senator FIERRAVANTI-WELLS—If you did receive any communication or advice to that effect, I would appreciate it if you could produce a copy of it. Thank you.

Ms Bennett—Okay.

Senator MOORE—I am focused on the role of consumers in the process, as you know. You heard my question to the consumer groups early. The PBAC does have a consumer representative on it—not a community representative; a consumer representative—under the current processes. Is there any link through the consumer network with that person in terms of understanding and getting information about what consumers need in the PBAC process?

Ms Bennett—The person representing consumers on the PBAC was nominated by CHF some years ago. It is now a ministerial appointment. That position is governed by the terms of confidentiality that are agreed upon on the appointment of that person. Therefore, it is very difficult for that person to consult broadly with consumer networks. Although they certainly do have access to consumer networks, they cannot consult on the detail of the committee deliberations. That makes that a very difficult thing for them to do.

Having a consumer representative sitting on the PBAC is one mechanism for involving consumers. It is fairly limited in terms of the scope of what that position can provide, and you cannot expect one person to deliver a consumer perspective on the whole range of drugs being considered by the PBAC. That is not possible. The confidentiality clauses in the terms of their engagement preclude that engagement.

So that is one mechanism and there are others. We are happy to provide you with some examples. Certainly we have been involved in consulting with consumers and developing consumer impact statements on particular medications that are being considered by the PBAC. That is another mechanism. Having the agendas available on the website is a good thing and enables the groups who have a particular interest to comment directly to the PBAC. There are also others. We will take that question on notice. We appreciate that question. There is a limit to what one representative can provide.

Senator MOORE—Having the agendas available publicly is something that people have talked about in a positive way. If people have a particular interest in a condition or pharmaceutical—we often hear about a particular one that people are seeking—is that then a way they can lobby the PBAC or its members about why it would be important to get x drug approved? Is that a process that your organisation does?

Ms Bennett—Generally speaking, the sorts of drugs that people are interested in lobbying about will be particular drugs for a particular condition. We would not necessarily be scoping the website and checking which drugs are coming up for consideration by the PBAC, but certainly some groups are. It is of great importance to some groups that their drug gets approved. So, yes, it is a mechanism for that lobbying to happen, but I would argue that that is a very good thing in that it does provide a greater level of evidence beyond clinical efficacy for the PBAC upon which they can make a decision. We heard this morning from consumer groups that clinical evidence is important and the scientific evidence is critical to the process and must be the basis

of decisions, but you also need that consumer perspective on how these drugs actually impact on them. That is a good mechanism to provide that.

Ms Wise—While we certainly welcome the publication of the agendas, as I think Carol mentioned earlier, many consumer groups are not for profit and have very limited resources so do not have the capacity to be monitoring the PBAC website to see the agenda. It is one mechanism.

Senator MOORE—The other issue we talked about last week in another hearing is consumer knowledge when talking with their practitioner. We heard evidence today about a consumer and their practitioner talking through what medication they should have and decisions being made about what they should do and the role of therapeutic groups in determining whether someone is forced onto one form of medication or another. In your experience, what is the knowledge amongst the consumer groups about their role in these discussions? Do they know they have the ability to talk with their practitioner about what medication they should be on, at what level, in what form and all those things? What is the level of knowledge of people about their own medication and the safety of that medication? I imagine you would like to comment on that.

Ms Bennett—Certainly it is variable. Not all consumers are informed and in a position to have that kind of conversation with their health practitioner. You could look at the therapeutic groups policy as an opportunity for consumers to have a conversation with their practitioner. Where particular drugs are interchanged that should absolutely be the basis upon which a discussion is had about the reasons for that interchangeability, any particular cost that may result from the provision of a different drug and certainly any side-effects or other issues that could potentially arise. It is an opportunity to do that. We would strongly encourage consumers to do that, but we would also like to see health professionals engage in that informed consent process.

Senator MOORE—The other process was where you can get the authority to have the dearer drug at the cheaper price. Do consumers know that their practitioner has the ability to apply for that? If they are told they have to have drug A because drug B costs more, do they know they can say, 'Why can't you ask for the provision?'

Ms Bennett—I would say generally no. We would certainly hope that practitioners are having that conversation with consumers and would use that option where they know it would be really difficult for people to afford the additional costs—and we are reliant on health practitioners to know somebody's circumstances, but we know they do not always know people's circumstances. That is an ongoing issue that we have in general terms about affordability.

Senator MOORE—Thank you.

CHAIR—Thank you very much. As usual, we very much appreciate your time and commitment to the Senate Community Affairs Committee's processes, because you participate a lot. Thank you very much. It is much appreciated.

Ms Bennett—Thank you, senators.

Ms Wise—Thank you.

Proceedings suspended from 12.29 pm to 1.24 pm

INDERJEETH, Dr Charles Anoopkumar, Member, Australian and New Zealand Society for Geriatric Medicine

MAJOR, Dr Gabor AC, Private capacity

OAKLEY, Associate Professor Stephen Philip, Private capacity

Evidence from Dr Inderjeeth and Associate Professor Oakley was taken via teleconference—

CHAIR—I welcome the next panel members. Do you have any comments to make on the capacity in which you appear?

Dr Major—I am here in my own capacity. I am the Director of Rheumatology in the Newcastle Bone and Joint Institute. As such, I have an ongoing interest in bones, osteoporosis and associated problems with fracture.

Prof. Oakley—I am a consultant rheumatologist, also from the Newcastle Bone and Joint Institute at the Royal Newcastle Centre. I have a conjoint appointment at the University of Newcastle. I am also here in my own capacity. As a rheumatologist I have an interest in the treatment of osteoporosis. I am also interested in research on osteoporosis.

Dr Inderjeeth—I am presenting in my capacity as a clinical academic at the University of Western Australia and as a representative of the Australian and New Zealand Society for Geriatric Medicine.

CHAIR—I understand you have all been given information on parliamentary privilege and the protection of witnesses.

Dr Inderjeeth—Yes, I have, thank you.

CHAIR—We have received submissions from you. I would like to invite each of you to make a short opening statement and then we will ask you some questions. We will start with Dr Major.

Dr Major—Perhaps I should explain briefly as to why I am here. I have an interest in and concern about elderly people breaking their bones, with the consequence that they become severely disabled. This is a national epidemic. We have, in New South Wales at least, almost $12 million a year being spent on people coming back with recurrent fractures. These are people who have already sustained a fracture and have a further fracture that requires hospital admission. There is an enormous gap between people receiving treatment and people who should be on treatment and are not receiving it. Only one in 10 of these people who should be on treatment is receiving it. There is a treatment failure. The first hurdle, in a sense, is that we have this issue.

The second hurdle is that we should be able to give the most effective treatment. It is clear that there are treatments that can reduce the refracture rate by 60 per cent. One of the paradoxes we have encountered recently is that some of these people who will benefit from the treatment will, later on, run into complications of the treatment. Our concern is that this may be influenced by

the choice of drug that we are using. We have some evidence that is strongly pointing in that direction and it concerns me that, if this ruling of equivalence is brought in, we may lock ourselves into a position that will be difficult to retreat from. My concern is on those grounds. I am also concerned that we should be treating these people as early as possible to make sure that we can intervene and stop the fracture cascade.

Prof. Oakley—One of the great challenges of the 21st century in Australian society will be managing the increasing burden of diseases of ageing, of which osteoporosis is one. Prior to the 1990s, we relied primarily upon calcium supplements, vitamin D and, in the case of post-menopausal osteoporosis, which is probably the largest group, we used oestrogen. Oestrogen is only useful for that group and it subsequently came under a cloud by association with breast cancer.

In the 1990s we saw the introduction of a highly efficacious class of drugs called the bisphosphonates, following large randomised controlled trials showing around 60 per cent reduction in fracture risk. We first saw alendronate, marketed as Fosamax by Merck Sharp & Dohme, and then risedronate, marketed by Sanofi-aventis as Actonel. It is important to note that in all these trials patients received calcium and vitamin D supplements. These supplements are essential for the efficacy of these drugs.

The introduction of bisphosphonates completely changed the treatment of osteoporosis. The patent for alendronate has now expired and we have seen the emergence on the market of less expensive generic brands. Risedronate remains under patent for a few more years and comes in combination packs with calcium and vitamin D, and the government is now seeking to reduce the cost of osteoporosis treatment by making these interchangeable. While I understand and support such endeavours, I would worry that these decisions are premature and the implications have not been fully evaluated.

I believe this is so for a number of reasons. The two drugs are not the same and differ in terms of chemistry and plasma half-life and, while bioequivalence between alendronate and risedronate has been demonstrated in terms of bioavailability and the clinical trials suggest that the two drugs have similar clinical efficacy, the key difference is in the end product, which comes with the supplementation of calcium and vitamin D. Currently, generics do not come with vitamin D or calcium and the doctor must remember to prescribe the supplement. The patients must then purchase vitamin D and calcium, which is not on the PBS, and then they must remember to take it, and we know that in real life compliance may vary and maybe only between 50 and 60 per cent. These factors—the additional costs and having to remember to take these medications—may further reduce compliance and efficacy considerably. We simply do not know.

The other concern that I have is one that Dr Major has already talked about—the emergence of these new atypical minimal trauma fractures of the shaft of the femur, or the thigh. The case reports have been emerging since 2005 and at present are almost exclusively linked to alendronate. There is fierce debate in the medical literature as to whether the phenomenon is real. There is also debate as to whether this is a class effect and seen with all bisphosphonates, or whether it is specific to alendronate. I really think that we need a number of years—perhaps five more years—to really work this out and we are going to require ongoing large epidemiological and laboratory studies for this issue to be resolved. On the basis of these points, I think that we

should really defer any such judgements regarding the PBS and subsidy for these medications. Thank you.

CHAIR—Thank you. Dr Inderjeeth.

Dr Inderjeeth—Thank you. I am presenting this submission in my capacity as a clinical academic and a representative of the Australian and New Zealand Society for Geriatric Medicine and I wish to comment on the proposal by the PBAC to create new therapeutic groups. Our understanding is that initially this will apply to bisphosphonates, and unfortunately it is possible that this may be rolled out to involve other therapeutic groups as well, which may have similar, if not worse, impacts on the treatment of other conditions.

We have a number of concerns to raise with regard to the potential adverse impact on patient treatment especially on older patients. We know already that the diagnosis of the condition is quite low. We know that patient and clinician awareness of the need to treat the condition is quite low. We know that when patients are treated about 40 or 50 per cent of them are likely to stop treatment within one to two years. Adding additional levels of complexity to treatment of existing choice may have an adverse impact on treatment of the condition that is quite important in terms of reducing morbidity and mortality and, more importantly, cost to health-payers.

The treatment choice is generally made by clinicians based on patient and clinician preference and is usually guided by cost, the risk-benefit ratio, and convenience, and this option will be taken away from clinicians. Clinicians also consider the special qualities of a particular agent in terms of the evidence of benefit in a particular subgroup of patients or patients with comorbidity and the potential interactions with other medications and diseases. The patients we deal with are generally the frailer, older group with multifactorial problems, with multiple medical issues and comorbidity, and polypharmacy, which is multiple medications they require for multiple medical conditions. In our belief, reducing the choice of the treatment of patients with a high-risk profile is fraught with risk.

Our concerns relate to the removal of the choice of the clinician and the patient to make a judgement on what would be the most appropriate agent for their particular disease profile, and this may impact on compliance. Notwithstanding the pharmacological differences of these agents, geriatricians would prefer to select agents based on good available evidence, efficacy and the onset effect and tolerability in the older patient groups. We tend to match the best profile of an agent with the requirement for the patient in terms of how soon we want it to work and what side effects and interactions there are with other treatments.

Current treatment selection for osteoporosis therapy is based on patient profile and factors that influence choice of dosage, frequency and modality of delivery. This might be impacted on by the new ruling. Currently, not all therapeutic groups are available across the range of dosages, frequencies and modalities of delivery and allowing interchangeability may impact adversely on this choice, which is made for specific indications. For example, the choice of less frequent dosing, such as monthly over weekly, is based on the premise that compliance, cost and convenience may be improved, and removing this option may adversely affect patient outcomes through reduced compliance and convenience and through the cost of formal or informal carers—that is, less frequent dosing may be preferred for patients who require supervision. A significant proportion of older patients have cognitive impairment or dementia syndromes and

require a carer to supervise their treatment. Hence, there may be advantages in less frequent dosing as these treatments require specific observation after treatment to ensure patients are not at risk of side effects from poor compliance.

Secondly, not all agents are available with complementary calcium and vitamin D, which you have already heard about. This is supplied by some but not all pharmaceutical brands. This is fundamental as the benefit of these agents has been demonstrated only in situations where calcium and vitamin D are optimised as well. Furthermore, these supplements are provided with combinations of calcium or vitamin D in dosages and combinations that vary widely. We tend to match combinations based on whether the patient also requires additional vitamin D, calcium or a combination. With the lack of standardisation across each of these pharmaceutical agents and their co-supply of calcium and vitamin D combinations there is potential for confusion, resulting in either diminished benefit or increased risk of incorrect combinations, causing overdosing and toxicity from incorrect or excessive supplementation. This is a real risk, especially in patients who are taking multiple medications for multiple medical conditions. We already have difficulty with poor compliance as well as excessive intake of medications, interactions and side effects.

Similar arguments may apply to other therapeutic groups, should the PBS choose to extend this to other therapeutic groups, including the treatment of conditions like cardiovascular disease, including hypertension, heart failure and diabetes. This is a major concern for us as well. We agree with statements made by prominent professional societies involved in osteoporosis, such as the Australian & New Zealand Bone & Mineral Society, and support the points as outlined in their submissions to you.

To summarise the view of our society, the new proposal is likely to disadvantage all patient groups but more so the older patient groups and may lead to poorer compliance and adverse outcomes, including fracture and toxicity. I think we need to prevent this type of legislation going through because it will have a negative impact when we are trying to treat the very conditions that we are trying to manage better and prevent, because currently we probably do not optimally manage these conditions.

CHAIR—Thank you.

Senator RYAN—Any of you should feel free to answer these questions because I have taken note of your verbal submissions and looked at your written ones. I gather that you have two concerns: one is the assumed interchangeability between the two bisphosphonates in this new group, but you also have concerns about patient interchangeability between brands within the genericised molecule. Is that a fair characterisation of your submission?

Dr Inderjeeth—Yes, it would be my assumption as well.

Prof. Oakley—Did you mean the femoral fractures when you were talking about toxicity? We are concerned about that particularly at Newcastle.

Senator RYAN—Could you explain that further? I was just referring to the fact that your submissions indicate that you are not just concerned with the grouping of—and I am not going to try to pronounce their names—distilled patented bisphosphonate—

Prof. Oakley—You are correct. I understand what you mean.

Dr Major—Our concern is primarily about the emerging possibility that the two bisphosphonates have different safety profiles and, in particular, they are known to have slightly different modes of action, so the extent to which they leach onto bone varies. Alendronate, for instance—Fosamax—is attached firmly to the bone for a long period of time, whereas risedronate is able to come off the target within six months or so, so there is a greater degree of reversibility.

We are seeing that both drugs are highly effective in preventing fractures, particularly hip fractures, which is one of the most devastating outcomes. But it seems there is a paradox. We are seeing fractures down the shaft of the thigh bone and this is an uncommon thing. The overall treatment is still worthwhile, but we are now starting to see this complication arise. It seems likely that this complication is preferentially linked to the longer-acting variety of bisphosphonate—the one that is harder to get off the bone. As Dr Oakley was referring to, there is a raging issue about it. Indeed, it is labelled as the hot topic in the American College of Rheumatology current releases as to whether this particular fracture risk is going to be a big problem for us or not.

People are walking along, they develop a bit of thigh pain and then all of a sudden the thigh just snaps straight through. It is a particular kind of fracture and, interestingly, one of the first case reports of this was in American by a doctor who had gone onto treatment in her 50s and continued as the treatment seemed to be going very well. Then she snapped one thigh riding on the subway and shortly after did the other thigh. It is a devastating event that is fortunately rare. We need to make sure that we understand more about it and that we are not locked into a situation where we have no choice but to use perhaps the less favourable drug. Time will tell. At the moment, I do not think we can claim this with certainty, but there are very strong indications for it.

Senator RYAN—So from a clinicians point of view—I would ask all three of you to comment on this if you could—do you consider these two separate molecules to be as interchangeable as just switching any other medicine? Would you want to switch a patient between them on one occasion or multiple occasions based on considerations such as price or the cost to the patient? Do you think these drugs should be considered perfectly interchangeable for patients?

Dr Major—I do not think they are interchangeable like that.

Prof. Oakley—I agree, although, as Dr Major says, time will tell whether these differences are significant.

Dr Inderjeeth—We tend to base decisions on treatment on the available evidence. Whilst it is difficult to compare different agents in situations where they are not directly compared to each other in a single trial, we base decisions on the outcomes and the efficacy of these agents. Firstly, we are fully aware that, for example, alendronate or Fosamax is a more potent bisphosphonate in reducing bone turnover. That may be desirable in some patients but not in others. Secondly, in terms of the bone density effect, there is a differential between the two. Thirdly, in terms of what we think is the onset of fracture effect, there may be some differences. For example, in older

patients you may want to choose a less potent bisphosphonate that has an earlier onset of action compared to one that is more potent and has longer term effects.

You will need to balance the efficacy in terms of reducing the fracture risk against the risk of potential toxicity from oversuppression of what we call bone turnover because these agents tend to reduce the rate at which bone is broken down. Older people and younger people are different so we tend to make different choices depending on the age and other co-morbidities in a particular patient. That is a choice that will be taken away from us if there is interchangeability. The short answer is that we perceive—and I am a clinician, not a basic scientist—that there is a difference in how potent and how effective these agents are in reducing what we call bone turnover as well as the risk of fractures and the timing based on the clinical literature. At this stage, we default to those judgements in making a judgement on when we would use a particular agent in a particular setting. That will be taken away from us.

Senator RYAN—We have heard from a number of other witnesses that, if cost was an issue to a patient through a therapeutic group premium, clinicians would have the opportunity to ring Medicare Australia and seek an authority because it was clinically inappropriate for there to be a change. Do you have any comment to make about that system, its accessibility, whether it is widely used and whether you use it or not?

Dr Inderjeeth—I certainly have not used that system to look for an agent outside of that group. It is substitution, I guess. I tend to specifically request a particular agent and tick the appropriate box to ensure that a particular agent is supplied to my patient.

Prof. Oakley—I was not aware of the system.

Senator MOORE—I am interested in the terminology that all of you have used about you being forced to change the medication that someone is on. I just do not understand why this particular process would force anyone to prescribe medication with which they were not comfortable.

Dr Major—To be quite frank, we are not forced into that. The issue arises because, say, if one decides to use risedronate as the treatment of choice, if the patient has to meet a price premium it creates an obstacle. As many of the people who are prescribed these drugs are elderly or pensioners and so forth, the extra cost can be a significant hurdle. That would be the main issue in that regard.

Senator MOORE—Were you unaware of the waiver process?

Dr Major—I certainly was not aware of what Senator Ryan was just outlining—that is, that we can ring up and request a special dispensation for the patient.

Senator MOORE—You can request that, yes.

Dr Major—That way, they will receive the requested drug—

Senator MOORE—Without the added cost.

Dr Major—Yes.

Senator MOORE—And none of you doctors were aware of that process?

Dr Major—No, I was not.

Dr Inderjeeth—No, and my concern would be that we are talking about a high-volume treatment. If we make a judgment that we want a specific agent then there is a specific amount of administrative responsibility that will go with this. Because of the volume of patients that we see that require a choice of one or the other of these agents, the administrative burden in trying to do that would be pretty problematic. We cannot assume that these two are interchangeable in clinical practice anyway.

Senator MOORE—Have you asked about it, to presume the administrative impost it is going to cause?

Dr Inderjeeth—I have never had to ask for it because, to date, we have been allowed to prescribe whichever agent we prefer. We have never had to do that in the past. If the regulation changes, we will be obliged to do that, which is going to increase that administrative burden. The biggest risk is that some clinicians may decide that the administrative burden is too much to make what they think is an appropriate clinical judgment. The default is saying, 'Whatever will be will be,' potentially to the detriment of the patient.

Senator MOORE—So the doctor would make an administrative choice over their professional choice of offering the service to their patient.

Dr Inderjeeth—That is a potential risk. Clinicians are generally time poor and sometimes they make a convenient decision which, as I said, may be to the detriment of their patient. They may have a particular preference. As I said in my dissertation, it was about patients and clinician choices and about matching a particular agent to the patient. But the problem is if it creates a significant administrative burden. I want to refer you to my other statement, which is that this is a condition which is already underdiagnosed and undertreated. If we add in additional administrative burdens, we will further restrict the rate at which patients are offered treatment because of the additional administrative work, or they may simply be prescribed an agent and it will be pot luck because you will get whatever the PBS chooses to give you, even though I may not necessarily think that is the best agent.

CHAIR—I have a family member who has quite significant osteoporosis. At the time of diagnosis, she was prescribed a drug that I understand you do not need to do this for now—and I cannot tell you what the drug's name is—but the doctor had to get permission to use it. It has just come off that list. So surely doctors are used to ringing up for drugs that in the past you have had to have permission to use? It is one of the ones that she uses once a week. I do not know what its name is, but I can tell you that the doctor had to get permission to use it.

Dr Inderjeeth—Thank you for that. One of the reasons that the regulation was changed was that it was seen as an unnecessary barrier to prescribing. We identified that only about 20 or 30 per cent of patients were getting that particular treatment. So by restricting it they are creating barriers for general practice. They are treating diabetes, hypertension and dementia, and

osteoporosis tends to be ignored. We know that this is not an inconsequential disease. There is a 20 per cent mortality rate. There is a 40 per cent disability rate, requiring nursing home care, and 60 per cent of patients require care. It costs $20,000 for a hip fracture. It costs $40,000 in a nursing home. These are potentially preventable conditions, or, at best, we can reduce the rate at which these complications occur. If we put in additional barriers they will not be treated. We know that they are badly treated already. Putting in additional hurdles will make it even less likely that they will be treated. We will actually be going backwards rather than forwards in terms of treating what we think is a treatable and/or preventable disease.

CHAIR—Thank you, Doctors. Your time is very much appreciated.

Dr Inderjeeth—Thank you.

[1.50 pm]

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

CHAIR—Welcome. I am sure you know the drill—in fact, I know you know the drill. I know that you also know about parliamentary privilege and the protection of witnesses and evidence. I invite you to make an opening statement and then we will ask you some questions.

Prof. Sansom—I have been the chair of the PBAC since 2001. The PBAC is a statutory committee which provides independent advice to the Minister for Health and Ageing regarding the listing of medicines on the PBS and on other related matters referred to it by the minister. The minister cannot list a drug on the pharmaceutical benefits schedule unless a positive recommendation is received by the PBAC. The expert members of the committee are medical practitioners, both specialist and general practitioners, a health economist, a pharmacist and a consumer representative. The PBAC is committed to full transparency and I have been attempting to achieve that for the 10 years of my term. The PBAC believes that submissions, evaluations and minutes of the PBAC should be in the public domain. Full transparency strengthens the process; it does not challenge the process. While there have been considerable improvements in transparency in this period, such as the publication of public summary documents and most decisions, there is still a way to go. We are continually dialoguing with Medicines Australia to progress this issue.

We have recently received permission from Medicines Australia to list the agenda for PBAC meetings six weeks prior to that meeting to allow input from the wider community, including from consumer and others. We have had discussions with consumer organisations to publicise this system. I note that there is debate within the department and it is looking at ways in which we can facilitate consumer input as a result of that system. Further, the PBAC holds stakeholder meetings involving clinicians, consumers and sponsors to progress difficult areas. In certain circumstances the PBAC also seeks consumer impact statements, seeking consumer comments on the questions: in living with this disease, what is it like for you, your family and your carers? Examples of where we have done this are for the disease social anxiety disorder and for sleep and restless leg syndrome. The PBAC also has regular meetings with a number of medical groups, including the Medical Oncology Group of Australia, the Australian Rheumatology Association, the Multiple Myeloma Research Foundation, just to mention a few.

In making recommendations to the minister the PBAC is required to take into consideration comparative effectiveness, comparative cost and thereby cost effectiveness. There is a difference in the role of the regulatory agency, whose task it is to evaluate the benefit and the risk of medicines and the TGA is not required to consider comparisons with other medicines. The important role for the PBAC is to consider the value-for-money concept. The majority of the committee's deliberations result from submissions from the pharmaceutical industry, although submissions from others, including consumer groups, medical groups can and have been received.

The PBAC considers how a medicine compares, both in regard to comparative efficacy and toxicity, with the medicine or other intervention that in practice it is likely to replace. If the new medicine shows that it is superior in health outcomes to its comparator then the sponsor will provide a cost-effective analysis and will usually, almost invariably, seek a higher price on which the PBAC will adjudicate, taking into account factors such as the robustness of the evidence, the clinical need and social values and the increased benefit and increased cost. If the sponsor is unable to show superiority but provides satisfactory evidence that the medicine is no worse than its comparator, in either efficacy and/or toxicity, it is recommended at the same price as its comparator to ensure that the system pays no more for the same health outcome. That is a statement that I commonly use in public: the same bang, the same buck. Mr Delaat, this morning, called it cost minimisation. It is the same thing.

The cost-minimisation approach is taken, irrespective of whether the medicines are a member of the same pharmacological class. They may in fact be medicines within completely different mechanisms of action but whose patient relevant outcomes are no worse than one another. The same outcome warrants the same price in the context of a funding or pricing program.

All the drugs within a therapeutic group are in the same therapeutic class and have been funded on the basis of being no worse than one another with respect to the dominant indication. The PBS system, as you know, is held in the highest regard in Australia and overseas. It provides an equity of access both in terms of universality and comprehensiveness, which is the envy of most countries. Drugs are often recommended in this country before other comparative countries and I give the example of Avastin for colorectal cancer as an example of that.

In regard to the formation of therapeutic groups, which commenced, as you know, in 1998 the PBAC has taken note of the relevant legislation. The PBAC considers the therapeutic group policy used by governments in regard to the cost of goods is an appropriate tool. The principle involves the concept of value for money and the purchase of health outcomes, which are the foundations of the PBAC processes. With respect to some of the submissions and statements by others at this inquiry there seems to be considerable confusion, even in the last presentation, between therapeutic group policy and brand substitution policy. They are two distinct and separate policies. The brand substitution policy allows substitution between brands of the same medicine which have been given patient and prescribed approval by a pharmacist. This is completely different from the therapeutic group policy, which is simply a pricing policy, which does not allow substitution by a pharmacist of a different medicine or formulation. There may be a requirement for the patient to pay a therapeutic group premium if the sponsor does not agree to any subsequent price reduction. Of the number of products currently involved in therapeutic groups, which equals almost 600, a brand premium has only ever been asked for six such products. That includes the company which manufactures the drug risedronate, which has been a topic of much discussion today. Thus, from the patient's and the prescriber's position, for the four new groups which we provided advice to the minister on, there would have been absolutely no difference in either what particular medicines from the group could be prescribed or the cost to the consumer.

The PBAC has interpreted the statement of the term 'interchangeable on a patient basis' in the following way: drugs within the therapeutic group are very alike—that is, they belong to the same therapeutic class and, in the vast majority of patients, would work just as well as one another. That is, in commencing a patient on any one of the drugs in a therapeutic group it would

make no difference in health outcomes for the vast majority of patients. This does not mean of course that each patient will respond exactly the same to every medicine in the group. Clearly, it is unrealistic to expect that. We are not clones of one another and individual differences will always exist in regard to both response and toxicity. Further, the history of the formation of therapeutic groups acknowledges that fact by allowing applications for exemptions from any therapeutic group premium. So to say that the interchange at the patient level has to be the same with each individual is not the way PBAC has interpreted this legislation at all. For the majority of patients, no specific characteristic is apparent which would predict that a patient may respond better to one medicine than another within a therapeutic group. That is unlike the situation, for example, with some anticancer drugs where molecular targeting may predict which patients will respond better to one drug than to another. Clearly, these types of drugs would be unsuitable for inclusion within a therapeutic group. I have informed Medicines Australia of the PBAC's interpretation of the term at the annual Medicines Australia-PBAC meeting and on repeated occasions to the officers of Medicines Australia. I have also informed that the PBAC does not have the capacity to make legal interpretations of acts or regulations. I have informed them of the interpretation that PBAC has taken of that piece of legislation—that is, interchangeability in a pragmatic way, taking into account the history since 1997.

A number of people have stated that the term 'bioequivalence' should be included in the context of the definition of 'interchangeability' as it refers to the formation of therapeutic groups. Even just a while ago you heard the term 'bioequivalence' between alendronate and risedronate. That is scientifically incorrect. Bioequivalence relates only to the rate and extent of absorption of the same drug in different brands. It is absolutely irrelevant within therapeutic group policy.

I would also like to take this opportunity to respond to some of the issues raised in the submissions, in particular with regard to the formation of therapeutic groups of bisphosphonates. A number of submissions addressed the issue of different mechanisms of action resulting in advantages for risedronate over alendronate. These submissions quote a review by Russell and others, published in *Osteoporosis International* in 2008. This review discusses the relative potency of the bisphosphonates with regard to different biochemical and cellular effects. Of course, what is relevant to patients is the impact on fracture risk or toxicity. What the submission fails to mention from this paper is the following conclusion by the authors of the paper:

Based on the available data, we have proposed that these differences might be clinically relevant, although additional work will need to be done to confirm these hypotheses.

Another statement relates to the onset of action of fracture prevention. In two of the submissions, the sponsor raised this issue. The major reference used to support the hypothesis that risedronate has a more rapid onset is a paper published by Silverman in *Osteoporosis International* in 2007. This paper used health record databases from the USA to examine the effectiveness of alendronate and risedronate on non-vertebral fractures in the first year of therapy. They examined records of 34,000 women and concluded that patients receiving risedronate have lower rates of non-vertebral fractures during their first year of therapy than patients receiving alendronate. The submissions, however, fail to report a more recent study by Cadarette published in *Annals of Internal Medicine* in 2008. Like Silverman and others, they used health record data from the United States. They concluded:

We found little difference in non-vertebral fracture rates among new recipients of alendronate or risedronate, regardless of the duration of observation (6, 12 or 24 months …

They went on to say:

Our results contrast with findings from other observational studies—

referring to the Silverman paper—

that document risedronate as more effective than alendronate …

They also went on to say:

Our large observational study of persons aged 65 years or older—

which would be the largest recipient group for these drugs—

who received drug treatment for osteoporosis identified no difference in the effectiveness of bisphosphonates (risedronate versus alendronate) in preventing non-vertebral fractures.

The editors of the journal, in a note to that paper, stated:

There probably is no single clearly superior drug therapy for osteoporosis.

The issue of mental health has also been raised at today's hearing. The only therapeutic group which involves drugs used in mental health is venlafaxine and desvenlafaxine—that is, Effexor and Pristiq. No other therapeutic groups exist for drugs used in mental health. The issue regarding the interchangeability of these two agents was discussed with the sponsor and their clinical expert at a hearing before PBAC in March 2009. We asked their clinical expert specifically whether there was any one patient that would benefit from this drug over the other. The answer was no. That is recorded within the minutes of the PBAC. It is interesting to note that the sponsor has recently withdrawn its application for registration of desvenlafaxine to the European Medicines Evaluation Agency due to concerns expressed by that agency. PBAC has sought advice from the TGA on this matter.

These examples demonstrate that there is uncertainty regarding some of the statements made to this inquiry. Uncertainty is not uncommon in many submissions, and the PBAC, in providing advice to the minister, has to deal with this frequently, using a risk management type strategy. The issue is whether, in the face of significant uncertainty, the funding agency should take all the risk or whether the responsibility is on the sponsor to provide the evidence to significantly reduce that uncertainty. In a teleconference with the Australian & New Zealand Bone & Mineral Society in December 2009, I made this point to the executive of that association. I encouraged them to provide any additional data to the PBAC for its reconsideration of the formation of bisphosphonate groups in December and January of 2009. The society has not provided any such data to the PBAC at this time.

The issue of vitamin D and calcium has also been raised. In March 2009 the PBAC recommended to the minister a combination product of alendronate, vitamin D and calcium at no

brand premium. We did so again in November 2009. There is to be a base price combination product of alendronate, vitamin D and calcium listed on the PBS schedule. In summary, I believe that the PBAC has been able to interpret the requirements for the formation of therapeutic groups and has the mechanisms and processes in place to investigate the evidence available, taking into account the uncertainty which is inherent within some of the data.

Senator FIERRAVANTI-WELLS—Professor, can I start by asking if you could outline for us the process. You have spoken about the process, but could you outline for us the actual process for the formation of a therapeutic group?

Prof. Sansom—The PBAC received a request from the minister for us to consider therapeutic groups in the following areas. We did that.

Senator FIERRAVANTI-WELLS—So firstly there is a request from the minister?

Prof. Sansom—Yes. In regard to venlafaxine and desvenlafaxine, I think the PBAC made it clear within the minutes of that discussion that we would not consider that there would be any difference between venlafaxine and desvenlafaxine. The request comes from the minister. The PBAC then looks at all of the publicly available data. It evaluates that data and makes a recommendation. The amount of material that the PBAC members evaluate is incredible. We receive information from the sponsors. People do their own literature searches and collect their own data and make what I would say are properly informed decisions on the evidence that is available, taking into account the uncertainty around some of that evidence. Nothing is ever black and white in this situation.

Senator FIERRAVANTI-WELLS—In the circumstances in relation to the therapeutic groups that we are talking about now, the requests came from the minister?

Prof. Sansom—In March we advised the minister that venlafaxine and desvenlafaxine could form a therapeutic group. In June we advised that oral bisphosphonate should form two separate groups, one for osteoporosis and one for Paget's disease. They were at the request of the minister. The PBAC looked at it. The PBAC discussed it and made a recommendation to the minister on those dates in relation to those therapeutic groups.

Senator FIERRAVANTI-WELLS—When was the PBAC first approached?

Prof. Sansom—I would have to take that on notice. All I know is that on 5 June we notified the minister and provided advice. Presumably it was before then. It could have been April, but I do not know. It could have been March. I would have to take that on notice. You might ask the department; they might know.

Senator FIERRAVANTI-WELLS—In terms of the timing of the release of the public information, is that purely a matter for the minister?

Prof. Sansom—No, I think this situation is somewhat different. As I said earlier, the PBAC believes that transparency is fundamental. In these cases of course it was in a budget context and that is up to the government and the minister. I do not think that is a question for me to answer.

Senator FIERRAVANTI-WELLS—That is the point—it was in the budget context. It came to you as part of a financial consideration, if I can put it that way.

Prof. Sansom—I suppose a lot of things in the PBS are to do with financial considerations. We are spending over $8 billion. It is a very rapidly growing section of the system. I presume it would be appropriate for any government to monitor that and seek advice as appropriate.

Senator FIERRAVANTI-WELLS—I appreciate that. It is also a source of savings when you are looking for money to save in the system.

Prof. Sansom—The sustainability of the PBS is fundamental to the future health care of this country.

Senator RYAN—I hope I have got the timing correct here. You considered these in the first half of last year at the first two PBAC meetings, but the sponsors of the medicines involved were told—if I have read the department of health submissions correctly—at the end of last year.

Prof. Sansom—In November, and then they were given the opportunity to provide further advice, which the PBAC considered.

Senator RYAN—At a meeting of the PBAC?

Prof. Sansom—At a teleconference of the PBAC.

Senator RYAN—I appreciate that these timelines are not always yours. It strikes though that, when forming these therapeutic groups, if you are using all of the available data, it would make more sense to initially approach the sponsors and potentially some of the clinicians and stakeholders to clear up some of the other issues you have mentioned in your verbal submission at the initial consideration, rather than giving almost a right of reply after a decision had been taken.

Prof. Sansom—Senator, you should realise that we have been looking at this data on these groups of drugs for nearly a decade. We have looked at alendronate. We have looked at risedronate. They have been here many times and there have been many submissions. We have seen a lot of this data previously. So it was not as if it was pulled out of the air de novo.

Senator RYAN—I appreciate your earlier comments and I know you have a long record of PBAC transparency. I also know there have always been ongoing arguments about it, but it strikes me that, when undertaking the consideration it might be easier—in fact, it could even save the PBAC time—to call in the relevant sponsors, stakeholders and clinicians and hear from them at the initial consideration rather than having the two-stage process.

Prof. Sansom—As I said initially, the circumstances of the formation of these groups were in a different context than usual.

Senator RYAN—I have one quick question and I suppose the answer will be a yes or no. These requests come from the minister. You mentioned earlier that the agenda for these meetings

is now public. Does that mean any subsequent requests from a minister to consider a therapeutic group would be on the publicly available agenda?

Prof. Sansom—You would have to ask the minister whether or not it would be on the agenda. My personal view would be that, yes, there should be no reason why not. But you would have to ask the department.

Senator RYAN—Who publishes the agenda when it goes public with this?

Prof. Sansom—The department publishes it.

Senator RYAN—So I can ask the department later on?

Prof. Sansom—Yes, I am sure that you can.

Senator RYAN—Do you approve that agenda before it is published?

Prof. Sansom—No, there is no approval. PBAC is required to look at everything before it. There is no selection of what the PBAC will look at. It is quite unlike many other agencies in the world. We are required to look at every submission.

Senator RYAN—Because these requests come from the minister, I will refer those questions to the department later on.

Prof. Sansom—I would prefer it if that went to the department.

Senator FIERRAVANTI-WELLS—Professor, I do not know if you followed some of the evidence that was given this morning.

Prof. Sansom—Yes, I did.

Senator FIERRAVANTI-WELLS—We talked about the various provisions in the legislation about the definition of interchangeability, and I will come to that in a moment. It is very clear from the legislation that the minister makes the decision, in the sense of the formation of the therapeutic group, and then comes to you. But it is very clear from the legislation that the minister does not necessarily have to follow your advice.

Prof. Sansom—No minister has to follow the advice. PBAC is a statutory committee; it advises the minister. The recommendation from PBAC is not binding on any minister and it never has been. It is always advisory to the minister. It makes a recommendation. Not all recommendations are accepted. I can remember one recommendation which was not accepted by the minister. I can remember one where we said no and the drug was funded outside the PBS system. PBAC is advisory to the minister. We are not a statutory authority; we are a statutory committee. That is not understood by many people. Many people believe that a decision by recommendation by PBAC is binding. The answer is it is not and never has been.

Senator FIERRAVANTI-WELLS—Just on that point, perhaps this might be the appropriate time to raise this: a number of the witnesses have indicated and expressed the view that you have

been put in an unenviable position. They have raised issues in relation to risk and confusion for the doctors and for the patients. Do you have a comment in relation to these concerns? What would be your response in relation to that?

Prof. Sansom—PBAC is an independent committee. It makes its recommendation without fear or favour. PBAC did not feel under any pressure here when asked by the minister about a question. Whether or not we believe that, for the majority of people, it would make no difference about which drug they were commenced on and therefore whether a therapeutic group should be formed was just normal process for us. We looked at the data, made a recommendation and that recommendation took into account the fact that there may well be some people that require one drug against another. An exemption is allowed for in the legislation. PBAC did not feel any more pressure on this than in any other decision. All decisions by PBAC are difficult. The easiest thing for PBAC members to do is always vote yes or whichever way. That is the easiest thing to do. Some of these decisions are not easy, but they are made in good faith, they take into account the evidence and they take into account the requirements under the act that we advise the minister about cost effectiveness.

Senator FIERRAVANTI-WELLS—When a drug is listed, you become aware of a whole series of information that is available about a particular drug. When the PBAC goes to make the decision that medicines are interchangeable as a part of the process, do you conduct a new evaluation for the formation of the therapeutic groups?

Prof. Sansom—Absolutely. In November and December we undertook a literature review of what was new and what had come out. It is just part of the normal process. PBAC does inform itself.

Senator FIERRAVANTI-WELLS—And that includes consultation with third parties?

Prof. Sansom—It can. For example, as I said, we used the consumer impact statement in some instances—not within therapeutic groups of course. There was confidentiality around the request to the minister because it was in the budget context. But in other cases, yes, the PBAC has sought input—and you heard the Consumers Health Forum this morning talking about the consumer impact statements. We would go out, if we believed that was necessary, and seek further advice.

Senator FIERRAVANTI-WELLS—Do I infer from that that it is possible you may have consulted with third parties in relation to these therapeutic groups but not consulted with the companies in question before the decision was announced?

Prof. Sansom—No. In reaffirming our decision with respect to the therapeutic groups, the risedronate people, Sanofi-aventis, put in a submission to us. That submission was looked at.

Senator FIERRAVANTI-WELLS—Not in reaffirming, Professor, in the original decision about interchangeability.

Prof. Sansom—The issue is that the minister asked for our advice in a budget context. This was not in the public domain—

Senator FIERRAVANTI-WELLS—The minister comes to you and in this case she says, 'I want to form a therapeutic group,' and she asks for your advice. If I understand correctly, without paraphrasing, you make your evaluation and that may include consultation with third parties.

Prof. Sansom—No, I did not say that. I said that third parties include industry, as is appropriate. But in this case it was within a budget context. PBAC had no right to go out. It was not in the public domain.

Senator FIERRAVANTI-WELLS—So if it is potentially a drug that is considered outside the budget process, you would have then consulted—is that what you are saying?

Prof. Sansom—We would have considered consultation. Whether that would have been necessary would have depended upon the evidence before us and what evidence we had.

Senator FIERRAVANTI-WELLS—If these drugs—whether it be Crestor, Lipitor, or the antidepressants or the drugs related to osteoporosis—had been outside the budget process and not been a decision purely associated with money in the budget process, then we probably would have seen a different process?

Prof. Sansom—No, you may have depending upon whether or not PBAC was satisfied with the evidence that it had available to it.

Senator RYAN—Professor Sansom, were you told that this was being done in the budget context?

Prof. Sansom—I think it was within the phraseology—and I cannot remember the exact words that the government used—

Senator RYAN—You were under the distinct impression that you were asked to review this in the budget context?

Prof. Sansom—The PBAC was aware that this information was being sought by the minister, and that information was to the minister.

CHAIR—Let me just clarify that. Any information that the minister asks you to review is therefore considered confidential or outside—

Prof. Sansom—We generally believe that the minister is after advice and we provide advice to the minister on the basis on which we make that advice. Submissions by third parties, apart from that, are quite a different scenario, I believe. I presume any minister can ask advisory committees for advice.

Senator RYAN—I appreciate that. You have mentioned the budget context quite a bit in the last few minutes and I am interested in exploring whether or not this request was made to you in the context of the budget, as opposed to whether you are asked for something in the month of July—and that might be different because there is no budget in the near future.

Prof. Sansom—I think we were told that it was in relation to a fiscal consideration around the therapeutic issues as they pertain to groups of drugs on the PBS at the moment.

Senator RYAN—You stated earlier that you are an independent committee and I appreciate—

Prof. Sansom—Yes.

Senator RYAN—that you are a longstanding member and I do not wish to cast any aspersions—and I will say that at the start. But it strikes me that you are an independent committee and you are asked to make a decision which, as you have said, was in the context of fiscal consideration you have described as being in 'budget context'. Therefore that is one of the reasons—not only, maybe, but one of them—that you are not consulting with external stakeholders, be they clinicians, the companies involved, stakeholder groups or patient groups, and then they hear about it six months later when they are given an opportunity post budget to have the decision reviewed. It strikes me that, if you are asked to do something in the budget context, that is going to weigh on your mind when you are thinking about it.

Prof. Sansom—No; it simply means that we will make the advice within the evidence that we have had previously and the evidence that now is in the public domain.

Senator RYAN—Why would that constrain your behaviour about consultation, then? If a decision on these medicines and therapeutic groups is being made absolutely purely on the evidence—and I respect you when you say that because of the longstanding traditions of the PBAC—then I do not see how the budget context is relevant, because there is either a scientific basis for the TGP or there is not. And if the minister is saying to you, 'I need you to do this in the context of the budget' then—I am not having a go at you, Professor Sansom, but I have got questions for the minister.

Prof. Sansom—They are issues you may wish to take up. The issue for us is that, when a submission comes in, that is in the public domain. The company knows about that. When the minister asks us for advice, that is asking us for advice. We look at the information. What the minister does with that advice and the way she or he manages that is an issue for the minister. You will have to ask the department.

Senator RYAN—One last factual question: when this was communicated to you, was it communicated to you by an official in the department or by the minister, in writing, or a ministerial staffer?

Prof. Sansom—I would have to take that on notice. I cannot remember exactly how it was that—

Senator FIERRAVANTI-WELLS—In relation to each group, could you—

Prof. Sansom—It would possibly have been in writing—I would have thought so.

Senator RYAN—I would assume it was.

Senator FIERRAVANTI-WELLS—Professor, can I just be clear: can you take that question on notice—

Prof. Sansom—Yes.

Senator FIERRAVANTI-WELLS—in relation to each group. We would appreciate knowing who contacted you, when you were contacted, when you first became aware, and the process that you followed in relation to each and every one of them, preferably in—

Prof. Sansom—Yes.

CHAIR—Can I also ask, for clarification: has this process changed under this government? Has it always been the practice for the committee that, if the minister seeks advice, it is done in the same way?

Prof. Sansom—Yes. The minister seeks advice—

CHAIR—So it has not been public? There hasn't been consultation? So there has been no change in process recently—is that right?

Prof. Sansom—No. The minister seeks advice; we provide advice to the minister, and we provide the context of the information that made up that advice.

Senator FIERRAVANTI-WELLS—No, but in relation to therapeutic groups—that is the issue. You should qualify that, Senator Siewert.

CHAIR—I know that you want to know about this specific episode. But what I am also keen to know is: when the minister has been seeking advice, in the past, whichever minister it has been, they have gone to you in the same sort of way, and you have provided advice in the same context of—

Prof. Sansom—Yes.

CHAIR—It is direct to the minister and you have not gone out to third parties?

Prof. Sansom—Yes.

CHAIR—Or was this one specifically different?

Prof. Sansom—No. The minister asked for advice; we provided advice to the minister.

Senator RYAN—Can I please finish my question?

CHAIR—Yes.

Prof. Sansom—I was just going to say that one of the pieces of advice to the minister may have been that wider consultation is required. But that would be the context of the—

Senator RYAN—The reason I asked the question, Professor Sansom, is that I am interested, effectively, in knowing where the request to you came from—was it via the department or was it from the minister personally?—and the form in which it came. As in the previous questions, this is not in any way questioning the work you have undertaken. Could I also ask—given that we have budget estimates coming up in only a fortnight—that that information, if possible, be provided, to allow the committee to investigate that further at estimates.

Prof. Sansom—I am sure it can be provided. It is just—as you can appreciate—

Senator RYAN—I understand. You cannot keep everything in your head!

Prof. Sansom—the amount of material; I mean, the last agenda was 43 kilos in weight, which gives you some idea! Just bear in mind that I cannot remember every detail.

Senator FIERRAVANTI-WELLS—You can appreciate why there is concern. I respect what you have just told us about the process you go through. And then you get a five-line public document—for example, the one on Lipitor and Crestor is barely five lines. So concern is understandable when there is a process that supposedly contains so much and then, at the end of the process, it does not really stack up in terms of transparency.

Prof. Sansom—If the minutes of the PBAC were on the website that would become available. I can assure you, the discussion document and the documentation that was discussed in that particular one you are talking about was very extensive, including quite extensive discussion about a diminishing margin of returns as you increased the doses and so on—very detailed discussion.

Senator FIERRAVANTI-WELLS—Well, Professor, perhaps not in this context, but after the evidence is concluded: there were some concerns that were raised and I think, in fairness—do you perceive that there could be some reform, or consideration given to a much more open and transparent process? You said at the beginning of your comments that certainly it is a lot more than it used to be, but do I understand that a lot more could be done?

Prof. Sansom—I do not comment on government processes or ministerial processes, but let me reiterate that I am not, and nor is the PBAC, scared of full transparency.

Senator FIERRAVANTI-WELLS—Thank you, Professor. Are your recommendations about therapeutic groups subject to independent review like other recommendations?

Prof. Sansom—Not that I am aware of. Again, I will have to take it on notice. It would not worry me if they were.

Senator FIERRAVANTI-WELLS—That would be helpful if you did have some sort of background.

Prof. Sansom—I do not believe that, under the agreement, these issues are subject to review.

Senator FIERRAVANTI-WELLS—What data did the PBAC use to assess the clinical risks to patients in considering these new therapeutic groups?

Prof. Sansom—What you look at is whether, for the vast majority of patients, it would make any difference which drug they had. The answer is that that information is contained within the body of literature which is in the public domain. As I said, there are many publications on osteoporosis, particularly if. that is the one you talked about, and with statins it is exactly the same. The PBAC looks at each one of those and determines whether or not there is a specific subgroup of people. As I said earlier, in certain cancer therapies you might identify a subgroup of people, but in statins, for example, we are spending one dollar in every seven of the PBS budget on statins. Where 95 per cent of the population can actually be managed irrespective of which statin they use, that clearly is an issue for the sustainability and total cost of which we must advise the minister. In this particular case, there are potentially one or two groups.

If you look at the submission from the Bone and Mineral Society, you see that they talk about a subgroup of people who perhaps are undergoing an organ transplant, with high-dose corticosteroids for a short time, where they would want to be able to stop the bisphosphonates after that exposure. That may well be a valid exemption. We did not get to the stage of recommending to the minister what exemptions might apply to these therapeutic groups. We were asked for advice about whether a therapy should be formed. We would presume that, if the process went forward, in due course the PBAC would have been asked for advice by the minister about whether exemptions, if any, should apply to these therapeutic groups. The PBAC would then have considered those issues which have been raised in the submissions.

Senator FIERRAVANTI-WELLS—In the Department of Health and Ageing submission, it says that in the vast majority of cases patients can move from one drug in the group to another without any clinical or financial impact. What is the cut-off point for determining the vast majority and what is the impact on patients who are not in the vast majority?

Prof. Sansom—The PBAC has interpreted this and we have had discussions. We would think between 90 and 95 per cent at least of people where it would not make any difference which one—we talk about the vast majority. If you have a subgroup of 40 per cent, that does not become a vast majority. We are thinking here of the order of 90 to 95 per cent plus and for all the evidence that is available with the group we have recommended, that would fit that category.

Senator FIERRAVANTI-WELLS—What does 'interchangeable at an individual patient level' mean and what definition do you use? Do you have internal guidelines that assist you in how you apply that definition?

Prof. Sansom—As I said earlier, the PBAC has interpreted the statement of the term 'interchangeable on a patient basis' as meaning that the medicines within a therapeutic group are very alike—that is, belonging to the same therapeutic class—and, in a vast majority of patients, they would work just as well as one another. That means that commencing a patient on any one of the drugs in a therapeutic group would make no difference to the health outcomes for the vast majority of patients. This does not mean that each patient would respond exactly the same to each medicine in the group. It is unrealistic to believe that that would be the case. We are not clones of one another and individual differences will always exist both in regard to response and toxicity. Further, the formation of the therapeutic group acknowledges that fact by allowing applications for exemption from any therapeutic group. That is the interpretation that PBAC has put on that.

Senator FIERRAVANTI-WELLS—That is your interpretation but there is—

Prof. Sansom—No, that is the PBAC's interpretation.

Senator FIERRAVANTI-WELLS—But there is no legislative definition..

Prof. Sansom—No. Again, let me go on. I do not know if you heard me, Senator, but I did say that I have informed Medicines Australia, who also have asked me that same question repeatedly, that the PBAC is not a group of lawyers, and the interpretation of that in a legal context is a legal issue.

Senator FIERRAVANTI-WELLS—Professor, do not get defensive. I think that there is a legislative deficiency, and that is why it has been canvassed at this committee hearing.

Prof. Sansom—The PBAC has looked at the history of it. You can provide exemptions; that means that it is not everyone—this is not an absolute. So we have interpreted that in what I would think is a pragmatic, commonsense way of proceeding forward with this policy, which has been in operation since 1998 and served the country well in relation to the PBS.

CHAIR—I need to move on to Senator Moore now.

Senator MOORE—Professor, I think a lot of the questions I have are actually for the department. But from your perspective—you have seen some of the evidence and the submissions—a lot of it relates to feelings of confusion and inability to get clear information about what is going on. My understanding of the PBAC is that you publish your minutes on the website.

Prof. Sansom—The minutes are not published.

Senator MOORE—But on the website there is—

Prof. Sansom—The public summary documents, which are based on the minutes.

Senator MOORE—That is right. That is public.

Prof. Sansom—While they are based on the minutes, they are not the minutes.

Senator MOORE—They are a summary document.

Prof. Sansom—They have been, in certain areas—

CHAIR—Massaged.

Prof. Sansom—To protect commercial-in-confidence issues, which is maybe not necessarily inappropriate at times. But they are based on the minutes, and they have been a major breakthrough in transparency.

Senator MOORE—How do individual sponsors exercise their rights to get more detailed information and feedback?

Prof. Sansom—After each PBAC meeting, if the PBAC has failed to make a positive recommendation I sit down with the companies, I go through their submissions and I go through why the PBAC rejected their submission and what needs to be addressed in moving forward. The PBAC will often give me authority to say, 'If you reduce the price to X then you can have a positive recommendation.' That is an ongoing dialogue, which has been going now for nearly 10 years, since I took over, and I think the sponsors have appreciated that. Remember that we have had only two reviews in that time. If you enter into dialogue with people after their submission has been rejected you can often find a way forward.

Senator MOORE—That is the process if they are putting up a drug for approval.

Prof. Sansom—Yes.

Senator MOORE—The supplementary process occurs if the drug is going to be included in one of the therapeutic groups. The concern felt by many of the people who were sponsors of drugs was that there was no advice or information given back as to why and how their particular product was included in the group, based on advice from the PBAC.

Prof. Sansom—That is true in a sense, but through due diligence the companies would have known that their drugs would likely have been subject to consideration of therapeutic group premium policy.

Senator MOORE—But nothing is given out to them stating the reasons?

Prof. Sansom—If the minister asks for advice, we provide advice to the minister.

Senator MOORE—So it does not come back through you; it comes back through the minister. If people are upset and have concerns about why their drugs are included in a therapeutic group, it is not an issue of complaint to you; it should be an issue of complaint to the minister.

Prof. Sansom—No. In this particular case, in November 2009 the sponsors were asked to provide additional evidence. One sponsor, I think, refused to do so, and one did so. That submission, which was submitted to us in November or December of last year, was looked at, all the issues were addressed and the recommendations were made to the minister. The department actually wrote to the sponsors. They had raised a number of issues. They were then asked to provide further advice to the PBAC, who would reconsider those issues. We did so and provided advice to the minister in January of this year.

As I said, I also received a number of letters from medical organisations. I had a teleconference with the executive of the Bone and Mineral Society. Again, they had misunderstood the policy: they thought the pharmacist could substitute alendronate. They confused brand policy and therapeutic group policy. I told them that if they had any further evidence surrounding the issues they raised about onset of action and these things that I have raised, they should provide it to the PBAC, which is always willing to look at new evidence. We

had not received any evidence, so we made the decision on the evidence that we had available to us—the evidence that we found in the literature, which had not been mentioned in any of the presubmissions. This is what we do routinely: with any submission, we do our own literature search, so it is not as if we are being cynical. The issue is that if the companies put in a literature search then we do a literature search to find whether there are disparities between the types of databases or the types of information upon which we might make a decision. In that context, we did in this particular case reconsider the material from Sanofi with regard to Actonel, or risedronate.

Senator MOORE—So there is no review process for that, as Senator Fierravanti-Wells clarified?

Prof. Sansom—Again, I do not think that is mentioned within it—

Senator MOORE—We will check with the department.

Prof. Sansom—You will have to check with the department.

Senator MOORE—Professor, you were not around in the 1998 process?

Prof. Sansom—No, Senator.

Senator MOORE—Lucky you.

Prof. Sansom—I was not appointed until January 2001.

Senator MOORE—I will follow-up with the department because I am trying to see whether there is a difference in the creation and the process from 1998 to now. A lot of evidence has been given to us—and you did address it in your opening statement—about the various bases of proof. A number of submitters felt that the proof test was not sufficient to prove interchangeability and that there should have been a more intense proof basis for the drugs.

Prof. Sansom—Interchangeability says: is the therapeutic outcome in any one group different from another? Virtually all of the papers and literature about osteoporosis suggest that there is no difference between the outcomes of any of the bisphosphonates. In fact, the submissions which we received from the sponsors to get listing of their drug stated that there was no difference; their drug was no worse than the comparator. In other words, as Will Delaat said this morning, the first thing the PBAC asks members of a group is: 'Were they all considered on a cost minimisation basis? Is there any evidence to suggest one is any better than another?' If they were, I can assure you that the sponsor would be seeking an increased price. Even on things like compliance, which has been mentioned two or three times today, the legislation quite clearly allows that, if a sponsor believes their drug improves compliance and that compliance improves health outcomes, that is a legitimate thing for the PBAC to consider in price-setting. No such evidence has been provided to the PBAC in this regard which is of a strength which would enable to us make that decision.

Senator MOORE—My final question is more an opinion, Professor, so if you do not want to answer it, that is fine. There has been a degree of opposition and claims of confusion and patient

disadvantage, even to the extent of very serious impacts on patients' health, raised as objections to this process. From your position as chair of the PBAC. Were you surprised at the degree of opposition and the statements that have been made in evidence about this process to this committee?

Prof. Sansom—Yes.

CHAIR—Senator, you have one question.

Senator FIERRAVANTI-WELLS—I do not have a question; I have a comment. I foreshadowed this morning that there would be evidence given this afternoon. Professor has given certain evidence and I think the department will also give evidence. In fairness, I think those appearing this morning in particular ought to be given the opportunity to respond and, if required, we should rehear some of those who come before us again. I would like to put that on the record.

CHAIR—I said this morning that we will accept supplementary submissions, and I expect to get supplementary submissions, and then we will make a decision as to whether we will hear them.

Senator FIERRAVANTI-WELLS—Thank you.

Prof. Sansom—I do apologise, Madam Chair, that I decided only last week that I should ask to appear because of what I had seen in some of the submissions. I finished the submission only last night. I apologise that it was not earlier. Mr Delaat said this morning that he had not received it, but I am sure, as I said earlier, that there is nothing in there which he has not heard repeatedly from me over many years.

Senator MOORE—Chair, can I put on record one thing before we move on: it is standard practice of this committee and always has been to allow the right of reply.

Prof. Sansom—I would expect that to happen. It is due process:

Senator MOORE—Any inference made by people listening to this hearing that that is not standard practice of the committee would be inappropriate.

CHAIR—Senator Ryan promises me that he has a short question.

Senator RYAN—Thank you. I was just thinking about the previous discussion. In considering this request from the minister about therapeutic groups in the budget context, when the sponsor companies were not considered in the initial consideration did the PBAC go outside the PBAC or the department of health and consult other third parties?

Prof. Sansom—No. It worked purely within the committee, within the evidence before it—the evidence that it got from the public domain.

Senator RYAN—Sure. That is all I have, Chair.

CHAIR—Thank you very much. We do appreciate your time.

Proceedings suspended from 2.39 pm to 2.48 pm

BESSELL, Mr Kim, Principal Pharmacy Adviser, Pharmaceutical Benefits Division, Department of Health and Ageing

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

McNEILL, Ms Felicity, Assistant Secretary, Pharmaceutical Evaluation Branch, Department of Health and Ageing

PRIMROSE, Dr John, Medical Adviser, Pharmaceutical Benefits Division, Department of Health and Ageing

STUART, Mr Andrew, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing

CHAIR—I welcome representatives of the Department of Health and Ageing. You will all be fully aware of the issues around parliamentary privilege and the protection of witnesses and evidence. As departmental officers you will not be asked to give opinions on matters of policy although this does not preclude questions asking for explanations of policy or factual questions about when and how policies were adopted. We have your submission. I invite you to make an opening statement and then we will go to questions.

Mr Learmonth—Thank you, I will make a statement. You have our submission but I would like to get on the record a number of things in relation to this policy. From our perspective there are significant errors and misunderstandings in the majority of submissions provided to the committee and I would like to take the opportunity to clarify some of those.

I would first note, as I think we have heard, that therapeutic groups—their creation and the pricing policy that underpins them—are not new. They have been used as a pricing policy by various governments since 1997, when the then government created four therapeutic groups. Since that time various governments have used therapeutic groups as a pricing policy to constrain PBS expenditure. There are now 523 brands of medicines in therapeutic groups.

From our perspective there are five key misunderstandings in the submissions. I would like to go through each of them, if I may. They are: firstly, that therapeutic groups require doctors to substitute one medicine for another; secondly, that pharmacists can substitute between drugs within a therapeutic group; thirdly, that patients will have to switch from a drug in a therapeutic group they need because of cost; fourthly, that drugs in a therapeutic group must be identical; and finally, that there was no consultation in the forming of the recent therapeutic groups.

Firstly, the presumption that doctors must prescribe differently because a drug is contained in a therapeutic group is wrong. The placement of a drug in a therapeutic group does not limit the range of drugs that can be described by a clinician to treat their patient. All of the listed drugs in a group are still available for prescription under the PBS, usually at the same cost to the patients—and I will talk more about that in a moment.

Secondly, the idea that pharmacists can substitute between drugs within a therapeutic group is also wrong. Pharmacists cannot substitute one drug in a therapeutic group for another. That is the brand substitution that Professor Sansom referred to. That substitution and that choice can only be done by the prescribing clinician. The requirement recognises that therapeutic groups include similar drugs that are interchangeable in the vast majority of patients and that not all drugs are exactly the same for all patients.

Thirdly, there are incorrect claims that patients will have to switch from a drug in a therapeutic group they need because of cost. In short, therapeutic groups are not designed to, nor do they inadvertently have, any impact on patient access to PBS subsidised drugs. The recently formed groups would not have resulted in any change at all to the cost of drugs for patients. It may, in fact, result in patients paying less in the future because for the past majority of drugs placed in the groups it can result in reductions in the cost to government and patients as subsidies are based on the lowest priced medicine in the group.

Fourthly, some have argued that drugs in a group must be identical. Again, this is a very significant misunderstanding of the intent of therapeutic groups. The inclusion of a drug in a therapeutic group is based on the expert opinion of the PBAC that the drugs in each group are alike and work just as well as one another for the vast majority of people. I think Professor Sansom made this point extensively and I do not propose to add further to that.

Lastly, the suggestion that there was no consultation in forming the groups is simply wrong. We did outline the consultation process in the submission. All affected companies and other interested people had an opportunity to comment on the proposed formation of each of these groups before a decision was made, and the formation of the groups was based on advice from the independent expert, the PBAC.

Therapeutic groups are entirely a pricing measure. The policy is designed to not have an impact on prescribing decisions or patient costs. There is no requirement that a drug in a therapeutic group be prescribed ahead of another, and the placement of a drug in a therapeutic group does not limit the range of drugs that can be prescribed by a clinician to treat their patient. All of the listed drugs are still available under the PBS. A patient may, in a small number of cases, pay a patient co-payment or, rather, a further premium amount, for a drug. I will talk more about that in a moment.

As I said, these recently formed groups would not have resulted in any change. None of the drugs in the four recent therapeutic groups had price premiums applied at the time the groups were disallowed by the Senate. Formation of the groups had no impact whatsoever on the price to be paid by the patients; it only reduced the cost to the taxpayer for supplying those drugs. And this is the common theme for formation of therapeutic groups.

I mentioned brand premiums. There are 523 brands of medicines currently within therapeutic groups. Only six of those 523 have a therapeutic group price premium and they range from $2 to $4.35 a script. If there is a therapeutic group premium on a brand of medicine, a doctor can, in consultation with the patient, consider the appropriate treatment and, if it is determined that another brand of drug is equally suitable, that other drug can be prescribed, which means that there will be no additional cost to the patient.

If there is a drug the doctor wishes to use that does have a therapeutic group premium, there are mechanisms in place to waive this. This is to ensure that patients do not pay a premium if there are clinical reasons for access to a specified medicine. All up, the formation of these groups has had no impact whatsoever on cost of or access to medicines for patients. The only outcome has been that taxpayers pay less and the PBS is more sustainable.

Chair, that was going to be my opening statement but, in light of perhaps some uncertainty and questions on issues around when and how and exactly what decisions were made about this and about the consultation, I would like, if I may, to ask Mr Stuart to quickly outline, end to end, just exactly what happened in order to help the committee and guide the questions.

CHAIR—You might as well because you are going to get asked about that anyway.

Mr Learmonth—I think it is a good starting point just to lay it out end to end.

Mr Stuart—There were five phases in the process that I will outline. The first was recommendation. The PBAC, as Professor Sansom outlined, makes recommendations not decisions, and so a recommendation was received from the PBAC in relation to the various therapeutic groups over the course of March to June 2009.

CHAIR—Can I just interrupt to ask: that was in response to the minister's request, was it not?

Mr Stuart—In response to the minister's request, that is correct.

CHAIR—I just wanted to find that out straightaway and get it on the record.

Senator FIERRAVANTI-WELLS—Whilst we are getting that on the record, perhaps you might like to tell us when the minister made the request.

Mr Stuart—We will have to take that on notice; we do not have that. I am talking about our consultation time line.

The MYEFO document, which publicly notified of the intention to form this group, was published on 2 November. Also on 2 November the department wrote to companies involved and to peak industry bodies conveying the intention to form the new groups and seeking comment. I would have to say that at the time some of the companies said, 'How dare you make a decision without telling us.' We had some of them come and visit me and I pointed out to them that this was not a conveying of a decision, this was a conveying of an intention, and we were asking them for comment. In other words, consultation started on 2 November. We wrote to the companies and peak bodies very carefully conveying the government's intention and seeking comment, so that is when the consultation phase started.

We then had letters from companies seeking reasons. On 3 December we wrote a number of letters to companies providing reasons for the PBAC advice. That went from the PBAC secretariat, as you can imagine. Subsequently, on 16 December and up to that point, there were a number of letters which raised clinical issues. The department's delegate, as the decision maker in this case, thought it wise to seek further advice from the PBAC in relation to the clinical issues raised.

This was actually the first time in forming therapeutic groups that clinical issues had been raised at that stage. So we had a little think about what do we do and we decided of course it was appropriate, in view of the fact that clinical issues were raised, that we seek the PBAC's further advice in relation to clinical issues. The PBAC then further invited companies to provide to it any other material that they wished to make available. On 8 January the PBAC provided further advice to the department's delegate in relation to the forming of these therapeutic groups. And it was not until 19 January that the decision was actually made by the department's delegate to form the therapeutic groups.

So: recommendation, March to June; conveying of intention and beginning of consultation, 2 November; decision on 19 January 2010 by the department's delegate.

CHAIR—Thank you. Does that conclude your opening statements?

Mr Learmonth—Yes, thank you.

Senator FIERRAVANTI-WELLS—Can I just go back. Obviously, under the legislation the minister must have made the decision to propose to create a therapeutic group and then she went off to the PBAC to seek advice. You cannot tell me when that decision was made? Do you want to take that on notice?

Mr Stuart—Yes, we will have to take that on notice.

Senator FIERRAVANTI-WELLS—Mr Stuart, I would have thought that that would be the first question you would know I would ask.

Mr Stuart—No. I have a whole time line with me. It does not go back quite that far.

Senator FIERRAVANTI-WELLS—So it was a considerable period before March 2009, was it?

Mr Stuart—No. What I have is a time line that is the chronology of events in relation to the making of the therapeutic groups, and it begins with the period that the PBAC gave advice. So I do not have with me, and I will have to take it on notice, the dates on which the PBAC was asked for advice.

Senator FIERRAVANTI-WELLS—If I understand the process, according to section 84AG, about therapeutic groups, the process starts with the minister determining or proposing to make a determination. So the process actually starts in the minister's camp. The minister is the one that initiates the process. Is that not correct?

Mr Stuart—I believe you are correctly quoting the provision.

Senator FIERRAVANTI-WELLS—Of course I am—I am reading it to you. My question is this. That is what the legislation says, so in your time line you have conveniently omitted the first point of this whole process, which is that if the minister proposes to make a determination under paragraph (1)(a) then she must obtain advice. So surely your time line must start from

when the minister proposed to make the determination, which was at some point prior to March 2009.

Mr Stuart—I have agreed to take it on notice and provide you with that information.

Senator RYAN—I asked you to take something else on notice with respect to that, which was: did the minister's direction to the PBAC arise from a recommendation from the department that preceded the minister's actual direction to the PBAC? I think this is a legitimate question.

Senator MOORE—I know. I am just thinking of how far we will go back here.

Senator RYAN—I do not want to come back and have the time line dating from the minister's letter, if it was a letter, and then find out how it got to the minister's desk. I doubt the minister sat down, picked up the schedule as they still print it and said, 'I'm going to come up with some therapeutic groups.'

Mr Learmonth—We will provide that information.

Senator RYAN—Thank you.

CHAIR—In other words, it is the back process we want an outline of.

Mr Learmonth—Yes. We will provide that. I think I understand what you are asking. We will try and cover that off.

Senator FIERRAVANTI-WELLS—You heard the evidence from the professor and the questioning of Senator Ryan. It is very clear from what the professor said that the formation of these therapeutic groups seems to be different if it is done in a budget context, as opposed to a non-budget context. That was very clear from the evidence that was given. Why is that the case?

Mr Stuart—As far as I am aware, these groups have always been made in the budget context and I believe that Professor Sansom also said that the process was consistent. As far as I am aware, the groups that were initially made in 1998 were made in a similar way.

Mr Learmonth—Professor Sansom can speak on his behalf but, if I may suggest what I think he was driving at, I think he was using 'in the budget context' as code for, 'The initiation of these things was taken in the context of budget confidentiality,' which applies not just to the budget per se but obviously also to MYEFO, when the last particular therapeutic groups were announced. I think it is more a reflection on the nature of the process that says that, when government is contemplating a fiscal measure of this nature, it is budget-in-confidence and thus it is not typically discussed outside the advisory arrangements to government until such time as the government, whether in the budget or MYEFO, makes its intent clear. Then there can be a process of consultation. Again, he can speak for himself and you can make judgment, Senator, but I guess I am trying to be helpful and explain what I think he was driving at there.

Senator FIERRAVANTI-WELLS—Did the previous groups that were formed include drugs that were still on patent?

Mr Stuart—The answer is yes, and we well try to find our place.

Senator FIERRAVANTI-WELLS—When you say you will 'try to find your place', what do you mean? You will try to find what they are; is that it?

Mr Stuart—Yes.

Senator FIERRAVANTI-WELLS—Were the therapeutic groups that were formed in 2007—and you have those set out in your submission—created as part of the PBS reform process? Is that the case?

Mr Learmonth—I am not sure that it is strictly true to say that they were created as part of the PBS reform process. I think there was some coincidence in timing, but the PBS reform process principally went to the creation of the two separate formularies—the statutory price reductions and price disclosure. I think that was the guts of it, whatever coincidence in timing there might have been.

Senator FIERRAVANTI-WELLS—Why don't we just have a look at it. Tell me about the PBS reform process. Is it delivering the significant savings to the government and consumers that were envisaged?

Mr Learmonth—In short, yes. There was a report earlier this year tabled in the parliament on the operation of the PBS reforms which provided evidence that the reforms were having the intended effect in so far as they were resulting in savings and a more sustainable PBS. They were in fact resulting on balance in cheaper drugs to consumers. They were not detrimentally affecting patient access and they were, with us, achieving the broad objectives that were set out.

Senator FIERRAVANTI-WELLS—So what are the estimated savings anticipated over the 10 years? I know there have been different estimates, but what is your latest assessment of those reforms over the 10 years? We have heard the figure of $6 billion over 10 years.

Mr Learmonth—Mr Stuart will probably have something more specific but there have been a number of different figures floating around. Some of them are rather larger than others.

Mr Stuart—PricewaterhouseCoopers produced estimates which have been published as an attachment to the minister's report to parliament. I cannot find the place in the report, but there was a lower and a higher threshold. From memory, it was between $4.5 billion and $6 billion, depending on what assumptions you make about price disclosure.

Senator FIERRAVANTI-WELLS—Suffice it to say that it has been a large process involving the stakeholders in the industry to achieve a very large saving. Everybody signed up to PBS reform. Of course there was a lot of consultation in relation to this with patient organisations, manufacturers, doctors et cetera. That was part of that process.

Mr Stuart—Just before we go on, I have now found my place on page 13 of the report. $3.6 billion to $5.8 billion was the estimate range from PricewaterhouseCoopers.

Senator FIERRAVANTI-WELLS—All right. I was just going to say that, in other words, the PBS reform process got the industry on board. When you look at the formation of therapeutic groups policy post PBS reform, there really has not been much consultation about it, has there?

Mr Learmonth—Therapeutic groups, as we tried to establish, are not new. The policy dates back to 1997. So you would not expect to have consultation around a very long-standing policy that has been applied by various governments since then. You would expect to have consultation focused around the application of that policy to particular circumstances.

Senator FIERRAVANTI-WELLS—What then has been the format of consultation in relation to the formation of therapeutic groups in the past? Have you had a consultation process?

Mr Learmonth—Do you mean the policy or the establishment of particular groups?

Senator FIERRAVANTI-WELLS—The establishment of them.

Senator MOORE—I think both.

Mr Learmonth—Mr Stuart and I were doing aged care reform in 1997. I am not sure we can tell you off the top of our heads about the genesis of therapeutic groups.

Senator MOORE—It is a really important point that these therapeutic groups have been in place for a long time and I am really keen to get information about how they were introduced and the process that happened around that time because they were a budget initiative. I think your submission actually talked about three different implementations of groups over the years. You did put it in your submission. We would like to know exactly what process was put in place by the government and the department to introduce those groups.

Mr Learmonth—Would it help if we provide on notice a history of how the policy first came about and when, and then something around the process of the formation of each of the groups subsequently, particularly focussing on consultation?

Senator MOORE—Yes, so we can see how it was done historically.

Mr Learmonth—We can step back and provide you with a comprehensive picture.

CHAIR—That would be really useful.

Senator FIERRAVANTI-WELLS—I would just like to move on to some of the comments that have been made about interchangeability. Based on the comments provided to this inquiry from healthcare professionals, there appears to be a number of risks associated with patients receiving different medicines, even generic versions of the same medicines. What assurance can the department give that there will be no risk to patients from these new therapeutic groups?

Mr Stuart—One of the key issues about therapeutic groups, as we have stated in our submission and our opening statement, is that they are a pricing measure. Therapeutic groups in no way change a doctor's authority to prescribe what the doctor believes to be appropriate for the patient. This is separate to brand substitution policy. Brand substitution policy is where two

medicines are an identical molecule and it is available to a pharmacist to substitute one product for another. Therapeutic groups are groups formed of medicines that are specifically not the same. In that circumstance there is no capacity for substitution and the doctor is responsible for prescribing the medicine that they feel is the most appropriate for the patient. So there is no risk to the patient from this policy.

Senator RYAN—I appreciate the difference and I appreciate your explanation. When you say they are a pricing measure, what that in reality means is that they are a means to reduce the price paid by the government for subsidies of medicines made available on PBS.

Mr Learmonth—What they do, like any other measure on the PBS, is try to introduce a principled and evidenced way of paying an appropriate amount to ensure the PBS is sustainable. The principle at stake is that taxpayers should basically pay the same amount for the same health outcome. That underpins an awful lot of what the PBAC does in terms of its job. The application of that principle rests on professional, independent and expert advice as to the circumstances.

Senator RYAN—As a taxpayer, I appreciate that approach. But they are introduced and they usually lead to price cuts for a number of products that are grouped together, don't they?

Mr Learmonth—Yes, they do.

Senator RYAN—So the aim of this process is to actually reduce the price paid by the Commonwealth for, as you describe it, what the PBAC determines are a class of medicines that provide the same health outcome across the population.

Mr Learmonth—Absolutely.

Senator RYAN—I think that is important when we talk about pricing measures. I just wanted to clarify that.

CHAIR—While we are on price, how much would the particular therapeutic groups that we are talking about at the moment save?

Ms McNeill—The three that were disallowed recently would have saved $48.2 million over four years.

CHAIR—That has come up a couple of times today.

Senator FIERRAVANTI-WELLS—The groups that we are talking about, how much is the estimated saving altogether?

Ms McNeill—The three that were disallowed were $48.2 million over four years.

Senator RYAN—You may have to take this on notice as well. I appreciate the PBAC is independent and it makes its decisions based on the evidence before it, as we heard from Professor Sansom. But in any advice to or from the minister in respect to this, I would be interested in knowing whether or not there was a financial target. In the minister's consideration of a direction to the PBAC to consider the establishment of several therapeutic groups, in advice

provided by your department to the minister, was there any target or such similar financial savings objective? Did it form part of your advice to the minister? Because that would then obviously, I would assume, be taken into consideration by the minister in her direction to the PBAC.

Mr Learmonth—The PBAC has never been asked for a financial target.

Senator RYAN—I am not asking that.

Mr Learmonth—It was not asked for a financial target.

Senator RYAN—I am not asking about the PBAC in this case; I am asking about the minister.

Mr Learmonth—I am sorry; I misunderstood.

Senator RYAN—If your department provided any advice to the minister that helped to formulate this direction to the PBAC to consider the creation of therapeutic groups, did any advice that you provided to the minister have a financial savings target or objective—because there may have been 10 or 12 possible alternatives? I am, to be honest, considering if the minister had been given a savings target to achieve out of the department of health and you had been asked by the minister or someone else to say, 'If you want to save this much money, here are four or five therapeutic groups you could establish.'

Mr Learmonth—You are asking us how we advise the minister, Senator.

Senator RYAN—Sorry?

Mr Learmonth—You are asking how we advise the minister.

Senator RYAN—Advice to the minister is not something that is generally not allowed to be asked and I will chase it up at estimates if I can. As far as I know, and I am new in this place, advice to the minister is not a general claim of immunity from questioning, cabinet documents are.

Mr Learmonth—As a general rule, our advice to the minister would cover most aspects of potential policies and their impacts, financial and otherwise.

Senator RYAN—It is not unreasonable then to conclude that part of the consideration of the minister in a direction to the PBAC may have been a savings target.

Mr Learmonth—Firstly the minister does not direct the PBAC. The minister asked the PBAC for advice. The minister does not ask the PBAC, 'Find me away of saving X amount of dollars.'

Senator RYAN—I appreciate that. I do not want to convey that. I suppose what I am trying to get to here is the PBAC is serviced by a branch within the department, as I understand it.

Mr Learmonth—The secretariat is within Mr Stuart's division, yes.

Senator RYAN—I do not want to allege anything here but if the minister had another target, absentia view or that had come out of somewhere that this committee is not allowed to investigate or as you described it 'budget in confidence' and there was a savings target that the minister wanted to reach for whatever reason and then the minister requested information from the department, which has access to quite a lot of information about this scheme, and then you provided advice to the minister that said the establishment of these groups—it could be four or five; I do not know how many; it could have been more or fewer—would lead to that particular savings target being achieved. That obviously, to me, is an issue for this inquiry with respect to the creation of therapeutic groups because they arose from a request by the minister for the PBAC to consider these issues.

Mr Learmonth—This is a fiscal measurement. I am not sure what you are trying to establish. This is a fiscal measurement announced by the government in MYEFO with the expectation that a certain amount of money would be saved.

Senator MOORE—Could we get the budget papers from 1998 from your department when they originally announced the budget measure for therapeutic groups.

The **Mr Learmonth**—I think it was 1997 that it took effect. We will give you whatever history we can come up with.

Senator MOORE—Can we get the budget papers about how it is presented, the proposed savings, over what period and what was the intent of the legislation. It would be very useful.

Mr Learmonth—Except for the fact that government accounting has changed, I think in that time it has been the same process. But yes, we will provide it.

Senator FIERRAVANTI-WELLS—In this particular instance it is interesting to see that the therapeutic groups under discussion really go to drugs which target two of the medical issues increasing the most at the moment. There is no doubt as to the increasing instances of mental health; we have heard the statistics and from Mr Crosbie and others this morning. Then with an ageing population you have got the other group that specifically addresses drugs that are pertinent to an ageing population. Who decided which groups are going to be targeted? Who made that decision? Is that a decision that initiates from Mr Stuart's area? Somebody woke up one day and decided that we were going to create therapeutic groups that affected antidepressant drugs and drugs that could potentially affect our frail and aged? It is a legitimate question. I would just like to know whose idea was it.

Mr Learmonth—Let me take issue with what I am inferring from your question.

Senator FIERRAVANTI-WELLS—Let me rephrase my question in a more direct manner. Who was responsible for deciding which drugs or which group of drugs were going to be targeted in the PBS?

Mr Learmonth—There are a couple of things. Firstly, whatever the use of the drug and whatever its benefit to whatever segment of society for whatever purpose, this is a pricing mechanism that does not affect the important outcomes that those drugs achieve for those patient groups. They do not affect patient access. They do not affect a prescriber's ability to prescribe

them and clinicians to use them how they see fit, and they do not affect the cost to patients. There is a suggestion there that these are important drugs and therefore should not be the subject of savings mechanisms. These are savings mechanisms that do not affect—

Senator FIERRAVANTI-WELLS—No, can I just clarify the intention of my question—that they are drugs that are increasingly being used in the community and therefore are probably more susceptible to being more used in the community and therefore are a better target if you wanted to undertake savings measures.

Mr Learmonth—I think it is incumbent if you are looking to ensure the sustainability of the pharmaceutical benefits system to ensure that taxpayers are best able to afford the continuing and substantial growth in cost of the pharmaceutical benefits system as new ever more expensive drugs are added to it year on year. It is important to ensure that, where we can, we look to make savings and allow taxpayers to make what share of efficiencies and savings they can from what is already on the PBS to create that head room and make the PBS more sustainable. This is a good way of doing it insofar as it does not affect patient access, it does not affect a clinician's ability to use which medicine they choose and think is appropriate and it does not affect the price to consumers; nonetheless, it improves sustainability.

Senator FIERRAVANTI-WELLS—They are your assertions but it is very clear that you are the only one saying that at the moment because most of the evidence we have heard all day contradicts what you say. Unless you were not listening this morning and into this afternoon, just about every witness has raised issues that go to patient concerns but you seem to be just dismissing that. You have come along here and said, 'This is all incorrect.' You have simply given us a bald statement that it is incorrect. Are you telling us that all the evidence we have heard this morning, particularly from doctors and other medical practitioners, has been totally wrong and you are the only one that is right? I just find your assertions and the evidence we have heard to be in direct contrast to each other—in fact, in direct contradiction.

Mr Learmonth—I think as both we and Professor Sansom were trying to point out, there are a number of misconceptions in areas of understanding in much of the evidence and the submissions that have been provided.

Senator FIERRAVANTI-WELLS—Mr Learmonth, thank you very much, and you are the—

CHAIR—Senator, can you allow Mr Learmonth to finish his comments.

Senator FIERRAVANTI-WELLS—Sorry. I withdraw that comment.

Mr Learmonth—We have attempted to explain, in some detail, why that is indeed the case in relation to access and conditions, rights to prescribe and cost to patients. If there is anything that remains a question we would be happy to go into it in any more depth you would like in order to substantiate our observations in relation to patient access, and condition and choice.

Senator FIERRAVANTI-WELLS—So you are saying that the practitioners we have heard from today are all wrong in their assessment and their concerns, particularly about pricing? We heard some evidence this morning that if a patient comes in to see a doctor and there has been a difference in price and their medication is now more expensive as a consequence of the creation

of this therapeutic group, the doctor says: 'This drug's cheaper; the PBAC says that I can interchange,' and swaps the medicine. You do not accept that evidence that has been given today?

Mr Learmonth—In relation to—

Senator FIERRAVANTI-WELLS—Are you saying that no drug that is now going to be put into a therapeutic group will be more expensive—is that the assurance that you are giving this committee?

Mr Learmonth—I can say several things. There are two aspects to that. One is about interchangeability; one is about price premiums, should they exist. In the case of the medicines which are the subject of the recent therapeutic groups, there were no price premiums requested, so it is not an issue.

Senator FIERRAVANTI-WELLS—You do not know that there will not be a price premium.

Mr Learmonth—I am sorry: there were none requested at their creation; it is a matter of fact.

Senator FIERRAVANTI-WELLS—But you do not know what is going to happen. You are making a decision now but you do not know that there will not be an increase in price, do you?

Mr Stuart—No increase in price was requested at the time the instruments were made. The department, at the time that the instruments were disallowed, had completed its price negotiations with the companies. No therapeutic group premium had been asked for. In that case, there would have been no therapeutic group premium applied to these products and not even any need to invoke the government's special provisions that save any potential effect on patients.

Senator FIERRAVANTI-WELLS—Now we are dealing with drugs that have a patent attached to them. You put them into a therapeutic group. Am I correct in the assumption that the price then comes down for all the drugs in that therapeutic group but the drug that is still on patent may still stay at the price it was at before—unless we misunderstood what the doctors were telling us?

Mr Learmonth—Senator, this is about price to government. If I could just—

Senator FIERRAVANTI-WELLS—No, we are talking about price to the patient. That is what I—

CHAIR—Hang on. We are talking about two different concepts, as I understand it. Can we just clarify the mechanism for pricing. The price that the patient pays is determined on the usual—

Mr Learmonth—Let me try to outline it.

CHAIR—The mechanism for premium—

Mr Learmonth—Patients—

CHAIR—Let me just finish the question. Take Senator Fierravanti-Wells' question as to whether the one on patent will be more expensive: do you still need to have applied for the premium in order for that to happen?

Mr Learmonth—Whether or not a medicine is on premium does not affect what price the patient pays. The only thing that might affect what a patient pays is whether or not there is a therapeutic group premium. There are on six out of 523 brands. They range from $2 to $4.25 or thereabouts. In this case none were asked for. If they were asked for, the doctor would be able, in consultation with the patient, to prescribe an alternative which would work just as well or, if the prescribing clinician believed that that particular medicine was important to the patient for a clinical reason, that additional therapeutic group premium to the patient could be waived. So the policy in relation to the pricing for the patient is extremely clear.

As to the question of interchangeability and conditions, confidence in that, you have heard from Professor Sansom. If I may, I will just very briefly quote the submission from the President of the Australian Medical Association, Dr Pesce:

> … the critical question is whether the respective medications are pharmacologically equivalent and therefore interchangeable at the patient level. The AMA considers that the PBAC has the necessary expertise to consider the relevant evidence and make this determination.
>
> The AMA is confident that the PBAC would have recommended the therapeutic groupings on the basis of the clinical evidence before it. If the companies that are affected by the Government's measure have new evidence that demonstrates their medications are not interchangeable with similar medications listed on the PBS, the AMA is of the view that this should be submitted to the PBAC for further consideration.

I think that is an expression of confidence in the ability of the PBAC to make appropriate judgments about interchangeability.

Senator MOORE—I have a question that may clarify the issue of guarantees. I know we never offer guarantees in anything, but once the negotiations are concluded with the supplier when the drug is listed and put in the therapeutic group, is there any opportunity after that for the supplier to come in and say, 'No, we want to change'?

Mr Learmonth—That is a broad question. In the case of what the government pays for medicines, always it happens in small ways through the Pharmaceutical Benefits Pricing Authority, which administers relatively small changes due to cost inputs to a medicine, and it is always open to a company to go back to the PBA, and they do regularly, to request a change in price of some other particular treatment and to present new evidence to support the case.

Senator MOORE—So it was negotiated when these were put up as a proposed group that this was going to be the costing, and it was all agreed and the PBS was going to be the cost, but at some time in the future a supplier of one of the drugs that is in this therapeutic group could come back and say—

Mr Learmonth—They could come back at any point and say, 'We shouldn't be in this group, and here is the evidence,' or 'Here is a segment for which we should be excluded.'

Senator MOORE—So we can say that, when the groups were put up, there had been costings agreed between the government and the suppliers—

Mr Learmonth—The prices, yes.

Senator MOORE—That was there, the prices had been agreed, but at some time in the future that could that change, with the supplier coming back and asking for a higher price?

Mr Learmonth—They could ask for a higher price. What they would be asking for is exemption from the group in some fashion.

Senator MOORE—Absolutely. But you cannot say, 'It's done and dusted and will never change'?

Mr Stuart—There are two mechanisms I should pick apart.

Senator MOORE—That would be good.

Mr Stuart—One, as David Learmonth is saying, is that they can come back to the PBAC at any time with new evidence that their product is superior and therefore come out of the group and obtain a higher price for the product on the basis of its superiority. They can also—and I think this is where your question was perhaps going—come back at any time and ask for a therapeutic group premium at a later stage.

Senator MOORE—They are the two mechanisms that could change the pricing that is known now?

Mr Stuart—That is right, and nothing has changed in relation to that.

Senator FIERRAVANTI-WELLS—Are either of those two decisions reviewable if refused?

Mr Learmonth—I am sorry—which decision? Do you mean the decision on whether or not to allow a therapeutic group premium?

Senator FIERRAVANTI-WELLS—On the two scenarios that Mr Stuart just outlined, is an adverse decision reviewable?

Mr Learmonth—An adverse decision in relation to what?

Mr Stuart—Are you talking about the ordinary process of judicial review?

Senator FIERRAVANTI-WELLS—Yes.

Mr Stuart—Departmental decisions are reviewable. Recommendations of the PBAC are not reviewable because they are not decisions, they are recommendations.

Senator FIERRAVANTI-WELLS—No, I am asking about the two instances that you just gave. If a company comes back to you and says, 'I want to opt out of the therapeutic group,' and you say no, is that decision reviewable?

Mr Stuart—The PBAC would have to recommend that it was a superior product, justifying a higher price, and they would have to provide that recommendation to the minister. That recommendation is not reviewable. Should a public servant make a decision—either yes or no—under delegation, that decision is reviewable.

Senator FIERRAVANTI-WELLS—Thank you.

Senator RYAN—Several years ago, I believe Pfizer had their particular atorvastatin delinked from the other statins. Was that an example of what you were outlining in the first case—that is, the PBAC recommending that it be given its own listing? I remember reading about it, and I am trying to put it in the context of the two decisions you—

Mr Stuart—My understanding of what happened at that time is that the PBAC gave further advice that there was a superior outcome from atorvastatin and therefore it should not be part of a therapeutic group.

Senator RYAN—So that is why it—

Mr Stuart—That is my understanding.

Senator RYAN—You mentioned earlier that a sponsor can outline that their product is different at a certain part of the patient population. One of the submissions we have here with respect to the bisphosphonates talks about a bisphosphonate with a listing on the PBS. I am reading from page 48 of the booklet, which is page 7 of the submission from Sanofi-aventis. It has a listing that the other bisphosphonate does not, and that is for treatment of patients on long-term, high-dose corticosteroids. If that is in a therapeutic group with another product but that product has a listing that the other product does not, how is that taken into account in this process?

Mr Stuart—The only time that that might matter is if there is a therapeutic group premium applied to one product and not the other. In this case no such premium was applied for, so the issue did not arise.

Senator RYAN—If one were applied for, how would it play out then?

Mr Stuart—We are in hypothetical territory now.

Senator RYAN—So this is an example that has not happened before? I thought there might have been a patient population that was different or distinct—

Mr Stuart—It has happened before. There have been recommendations from the PBAC a number of times where there are somewhat differing indications for the particular drugs included in the group. I am unaware of whether that was ever impacted by a therapeutic group premium. Someone might have a look. Only in that case would there potentially be an issue, and then there

are still policy levers available to the department to make sure there is no impact on the patient of that therapeutic group premium.

Senator RYAN—And that would be along the lines of a prescriber requesting the authority form Medicare Australia to waive the therapeutic group premium?

Mr Stuart—That is a key policy lever in that case.

Senator RYAN—What other possibilities are there?

Mr Stuart—Should we think that there was a significant patient impact, we could also accept that indication for the purposes of the therapeutic group.

Senator RYAN—Does that mean it gets calculated into all those weighted average costs in some different way? I am not quite sure what you mean by that statement. I appreciate that the calculations of price here are quite complex. I just want to know how a distinct patient population and a listing of one product but not another in a group is taken into account.

Ms McNeill—Let me clarify. The act provides that the minister can determine circumstances in which the Commonwealth is to pay the special patient contribution for the brand of the pharmaceutical item. We have four standard criteria that are in the PBS already. In the circumstances that you have outlined, if that situation had eventuated the government would have had the opportunity to consider the issue of patient access and whether further exemptions from the payment of the premium may have been appropriate in the circumstances.

Senator RYAN—So the only real option is if the company or sponsor puts on a therapeutic group premium. Then there would be an ability for the prescriber to get that waived because the patient fit the exact listing and, therefore, the other product in this bisphosphonate group was not appropriate for them. Is that the way?

Ms McNeill—Are you asking how you get a separate indication?

Senator RYAN—No. There are two listings here for the two bisphosphonates. One of the bisphosphonates has a listing which the other one does not, and it refers to patients on long-term, high-dose corticosteroid. This means that for that group of patients these presumably are not interchangeable products if one is listed for that purpose and the other one is not. I wonder how that is taken into account when the pricing is determined. It is two different varieties of apple, if you will, rather than two granny smith apples; it is not quiet an apple and an orange.

Mr Stuart—To clarify, while one of the drugs is listed for a particular indication for which the other one is not, they are still therapeutically equivalent. The fact that the other one is not listed is simply an outcome of the fact that the company has not applied to be listed for that indication, not that it is unsuitable for that indication.

Senator RYAN—No, but the PBAC, if I am correct, takes the approach: 'You show me the evidence and then I pay you for it.' So we could have a wonder drug out there but, in the absence of a submission being made to the PBAC—usually by a sponsor, but it can be made by someone else—and in the absence of the evidence being provided, it does not matter for the purposes of

the PBS and for subsidy from the Commonwealth taxpayer. I thought the PBAC's approach was: when the evidence is there, that is when a product is subsidised or the sponsor company is rewarded. There is not the assumption: 'We don't have the evidence but we'll still give you credit for it'—the bang for your buck that Professor Sansom mentioned. In this case, however, you seem to be saying the opposite: just because it does not have the listing, that does not mean the product does not work in those patients. I agree with you, but it is not being paid for that, is it? The health outcome has not been justified through the PBAC process for that particular patient population.

Mr Stuart—I am not exactly sure about what you mean when you say, 'It isn't being paid for that.' I am just pointing out that the drugs are interchangeable on an individual patient basis and that was the recommendation of the PBAC—

Senator RYAN—So this is something we should chase up with—

Mr Stuart—and the fact that one drug has a particular indication and the other one does not is simply an outcome of one having been applied for by one sponsor and the other not having been applied for by another sponsor.

Senator RYAN—To be correct, Mr Stuart, it is not an indication that one has been applied for. I do not know whether the other company applied for it and did not get it. It is actually an indication of a decision by the PBAC that the evidence exists for that listing, surely. It is not evidence of an application; it is evidence of a PBAC decision. To me that is a logical distinction.

Mr Stuart—We are probably moving increasingly further away from the core subject, but I did want to clarify that the drugs are actually therapeutically equivalent, whether or not the indication has been approved by the PBAC.

Senator RYAN—Mr Stuart, as long as the chair lets me, I will pursue this question.

CHAIR—We have until four o'clock.

Senator RYAN—It is not an indication of an application. It is an indication of a PBAC decision, is it not? There are plenty of applications the PBAC either does not take on face value or rejects. This listing—I just want to clarify this—is a PBAC decision, not an application for listing.

Mr Stuart—I am at risk of getting into Lloyd Sansom's area of expertise rather than my own.

CHAIR—Could it not be both, Senator? There is a particular drug that I have been following up for constituents and I have been told the sponsor simply has not applied for it.

Senator RYAN—I understand that. That is my point. The yellow book, as it used to be called, is a compendium of decisions by the PBAC. It is not a compendium of applications by sponsors. I would suggest that would be a substantially bigger book because the PBAC makes decisions based on applications—yes, no or maybe. I am happy to move on to the question that Professor Sansom asked me to refer to the department. He indicated the coming publication of the agenda of PBAC meetings was the result of an agreement between either himself and Medicines

Australia or the department and Medicines Australia—I cannot quite recall. This was on the agenda for PBAC meetings. Will future consideration of therapeutic groups be on the publicly available agenda for PBAC meetings? He asked me to refer that to you, hence the question.

Mr Stuart—I believe that will depend on the circumstances in which the minister is asking for advice. I believe that the minister is entitled to ask the PBAC for advice on a confidential basis. The establishment of the PBAC certainly allows for that. While there are very significant conventions which have grown up about the public availability of information about the work of the PBAC, the minister is still certainly entitled to ask the PBAC for advice on a confidential basis.

Senator RYAN—So, if the PBAC were, of its own accord—not due to a request from the minister—undertaking some work on therapeutic groups, that would appear on the agenda?

Mr Stuart—We probably have to take that one on notice. It depends a lot on the circumstances.

Senator RYAN—If you are going to take it on notice, I would appreciate some guidance—because I will probably come back to this during the budget estimates—about what the criteria would be for it appearing or not appearing on the agenda. I appreciate the point that the minister is entitled to request confidential advice. However, some guidance would give clarity, were this situation to arise again in, say, two years time. It may save a lot of time. If something had been considered but it had not appeared on the agenda, we could just say, 'One of these three criteria meant we didn't know about it beforehand.'

Mr Stuart—I am happy to take that on notice. The head of the PBAC secretariat has left with Professor Sansom; otherwise I might have been able to answer that now.

Senator RYAN—Would it be a cost to the budget to either lift or remove the cabinet threshold for consideration of medicines recommended by the PBAC?

Mr Stuart—I think the primary thing it would do is remove from cabinet scrutiny an additional area of expenditure.

Senator RYAN—You do not think it would cost the—

Mr Learmonth—Senator, you are talking about internal governance arrangements and how the government chooses to make decisions.

Senator RYAN—No, this is a factual question: does the department have a view or is it doing any work on whether or not there would be a cost to lifting or removing the cabinet threshold for consideration of PBAC recommendations?

CHAIR—What has been put to us is, as you must know, raising it from 10 to 20 million and what impact that would have.

Senator RYAN—I am genuinely asking. If someone says there is a cost to the taxpayer out of doing that, then fine, and that is a reason we could take into consideration.

Mr Learmonth—I cannot say we have thought about that particular question. Certainly the process of all the representations on changing the way government makes decisions about funding medicines is a regular topic of discussion with Medicines Australia. The government has chosen to make decisions in the way it does and regards it as good governance internally. The question of cost I cannot say we have ever considered. I would like to think about that, if I may.

Senator RYAN—Sure, and if you have anything on that I would appreciate it, or if the department has undertaken work on the perceived cost of lifting this from 10 to 20 million or to any other number, or to removing it because it specifically relates to the terms of reference of this inquiry.

Senator FIERRAVANTI-WELLS—Evidence was given earlier about a medication given to Medicines Australia by the then opposition—now the government—in relation to reviewing the 10 to 20 per cent threshold. As part of the brief to the incoming government, was that one of the issues that would have been covered?

Mr Learmonth—I could not possibly recall that.

Senator FIERRAVANTI-WELLS—Could you take that on notice and, if there are any documents in relation to that, advise us. I have asked the same question of Medicines Australia. They were going to produce any correspondence or anything they may have from the department or otherwise. I similarly ask you if you could you take that on it.

CHAIR—We need to go to Senator Moore.

Senator FIERRAVANTI-WELLS—If I could ask the department to take one question on notice: you heard earlier the evidence about the definition of 'interchangeable at an individual patient level'. You may have followed some of the earlier questioning about the lack of legislative definition of that phrase. It is very clear from the legislation that there is no definition of what is interchangeable at an individual patient level.

Mr Stuart—We do not believe that to be the case. We believe that the criterion to be applied in this case is that the experts in the PBAC judge and advise that the drugs are interchangeable on an individual patient basis, that that is the criterion, that it is relatively simple and straightforward and the PBAC has every confidence that there is really no need to make it more complicated.

Mr Learmonth—We will provide a full answer for you on notice, Senator.

Senator FIERRAVANTI-WELLS—It is a rather circuitous legislative power which goes from one provision to another but, I would have thought, given what the professor told us earlier, that it is his interpretation of it. I could not find any legislative definition. He has obviously interpreted what he thinks it is. Is that the definition?

Mr Learmonth—We will provide an answer on notice. One thing I would say is that there is a balance to be struck sometimes in how you regulate and define these things because this is an evolving landscape—the science, the clinical evidence. An awful lot of things evolve and there needs to be some capacity for judgment and expert clinical advice to be applied to circumstances

which may arise differently from in the past. There has to be some flexibility in the system. We will do our best to answer your question on notice.

Senator FIERRAVANTI-WELLS—Senator Moore asked you to take a question on notice earlier about the issue in 1997. In particular, could you also outline the provisions that were made by the then government to an education campaign to minimise confusion and risks to patients, which I understand was also done at the time of that introduction. Could you provide us with details, if you have those available.

Mr Learmonth—Do you mean therapeutic groups and not brand substitution?

Senator FIERRAVANTI-WELLS—No, I am talking about therapeutic groups.

CHAIR—When they first came in.

Senator FIERRAVANTI-WELLS—In 1997-98.

Mr Learmonth—I understand that. It just sounded like brand substitution is all.

Senator FIERRAVANTI-WELLS—Also, the first groups that were proposed in 1997 included two groups that were never formed. I think when you go into the history you will find that this Senate, in particular on 4 June, examined and went through some of those processes, particularly involving antidepressant drugs, which revolved around some patient concerns. There was some crucial information on patient risk that was put forward during consultation on the antidepressant therapeutic group in the late 1990s—in particular, evidence that was given by Dr Whiteford. My question to you is: given Dr Whiteford is still in the department and given the evidence that he previously gave, was he at any point a consultant in relation to the therapeutic groups that are now being formed which clearly involve antidepressant drugs as well? Could you take that on notice. His evidence on the last occasion was most helpful in that we did not proceed with those therapeutic groups, so I would be interested to know if he was consulted on this occasion to be equally as helpful to the department in its considerations.

Mr Learmonth—I will certainly do that. Whether he was or was not, I am sure the PBAC availed itself of the appropriate expertise—independent expertise as opposed to departmental employees.

Senator MOORE—I have not got many questions. You are taking on notice for Senator Fierravanti-Wells about the definition and process, but a number of the submissions have baldly stated that they have attempted to get a definition out of the department and have been unable to get a response on that. In your question on notice, can you put some effort into that. It is a very definite claim that has been made by a number of people—that they have not been able to get satisfaction from the department on that.

The other thing that worries me is the amount of evidence we have had today where people were talking about this situation and did not understand the process of the relationship between doctor and patient about the ability to prescribe and seek support. A number of people have indicated that they feared that there would be all kinds of price impacts for patients when under the proposal there was none. That concerns me.

I am picking up Senator Fierravanti-Wells's comment about education. What is the process for advising practitioners, particularly general practitioners, about how these systems work? Is that coming through the PBAC? Is it coming through the department? Is it coming through Medicare? Where do people go to understand the process to know what drugs are listed, what costing process is used and how a therapeutic group operates, particularly, as I said, while already operating in the system?

Mr Learmonth—The full answer will come, but mostly pricing the PBS is invisible, and that is fine because it does not impact on anything a doctor is prescribing or what patients pay. In the context of this, the therapeutic group premiums would be the circumstance.

Senator MOORE—But a number of doctors did not seem to understand. All the information on the proposed therapeutic group was out March last year. It was all there about how it was going to work. They did not know. Their evidence actually showed that they thought there was going to be an impact on patients at quite a serious level. Some quite serious statements were given in evidence today about the proposed impact on patients in this process. I am just wondering about how the information is shared with general practitioners about how a therapeutic group operates.

Mr Stuart—There are three parts to that reply. Firstly, there are some subtle bendings of accuracy in some of the submissions from people who understand this policy very well.

Senator MOORE—I am certainly going to quote you, Mr Stuart, with your 'subtle bendings of accuracy'.

Mr Stuart—Also, I think you need to allow for the possibility that there has been some spreading of subtle bending which has not been received in a subtle way by some of those that might have given evidence and that there are those in this space who have some incentive to provide information which may not be entirely accurate.

Senator MOORE—Could there also be a genuine misunderstanding?

Mr Learmonth—We will provide some advice to you on how that works, Senator.

Senator MOORE—That would be useful.

Mr Learmonth—Again, this is not new. I think GPs, by and large, understand it well. They have been dealing with it for more than a decade. As I say, there are 523 brands of medicine already. They know how it works.

Mr Stuart—We can just speak to how the information is provided.

Senator MOORE—How is it put out?

Ms McNeill—If we take, for example, one of the groups that does have a drug with a therapeutic group premium in it—the angios for cardiovascular—every month when the PBS is published there is specific outlining of the authority required that can be applied for by the physician to get the exemption from the therapeutic group premium for the patient. We also have

material on our website, pbs.gov.au, for both clinicians and patients about what therapeutic group premiums are and explaining that there are exemption criteria that can be applied for where it is clinically appropriate to do so.

Senator MOORE—And also the issue of confusion with doctors—and I refer you to the evidence about the dosage and how it would operate and all those kinds of things. My understanding is that with every medication there are clear instructions both in paper form and in email—and, Dr Primrose, this could well be your area—that are very clear about what the dosage amounts are, how they operate, how they interact and all those kinds of things. That is all there for people to understand.

Mr Stuart—The core problem here is that the impression has been created that the doctors need to substitute something for something else. They do not. Under this policy they go on happily prescribing as they have always done, using the same products in the same formulations and at the same strengths as they have always done and referring the patients to the patient information within the boxes of preparations as they always do.

Senator MOORE—And, Dr Primrose, that is all there—part of the process?

Dr Primrose—Yes, there is clear advice regarding dosage in the approved product information for each drug. There is also the summary information in the *Australian Medicines Handbook* and also in the Australian therapeutic guidelines. So there is no shortage of high-quality advice to guide doctors in dosing. Generally, according to the principles of quality use of medicines, we advise the doctors to start at the lower end of the dose range, have a clear target for therapy in mind and then gradually increase the dose until that target is met provided there is not toxicity encountered in doing that.

Senator MOORE—We had particular evidence that there was one drug which had other aspects—it added vitamin D and things like that. So the difference of each compound is clearly put in the process?

Dr Primrose—Yes, that is right, and the doctor would need to make a decision on whether a maintenance dose of vitamin D and calcium is appropriate or, in fact, whether the patient is vitamin D and/or calcium deficient, in which case they would need to have replenishment of the stores of that vitamin or mineral. So it is not a case of one size fits all.

Senator MOORE—And none of that is impacted by a therapeutic group?

Dr Primrose—No, that is a matter of good clinical judgment and good prescribing.

Senator MOORE—Thank you.

CHAIR—I have one or two questions you may want to take on notice. I will also put on notice that some issues have been raised today and in submissions that probably are not necessarily specifically relevant to the terms of reference but are relevant to other issues in terms of people being able to access pharmaceuticals. So I will just let you know that I will be asking those in estimates, in view of the time.

The specific issue I wanted to talk to you about now is to go back to the time line; perhaps you could explain the time line. As I understood it, between March and June there was the consultation process with the PBAC and then you did not release the intention to form the new TGs until 2 November. What was the time delay? It was from June to November. Why was there significant time delay? Was that a departmental process? Was it a process where the department and the minister consider it?

Mr Learmonth—Whether or not to decide on such an intent and the timing of its announcement is a matter for government decision.

CHAIR—So it was a government decision that they took that time to consider it?

Mr Learmonth—It is a fiscal measure, so typically it would have to come at either the budget or MYEFO. November was MYEFO, wasn't it?

CHAIR—Yes, you issued it in November.

Mr Learmonth—But that was MYEFO.

CHAIR—Which was the intent, where you started—

Mr Learmonth—That is where the intent and the consequence, the fiscal impact of that, were reflected—in MYEFO. It would have to be. Because it was a fiscal measure it would be either budget or MYEFO.

CHAIR—When you are seeking comment from the MYEFO process, how does that get to consumers, for example? Are they included in that process, or is it just the pharmaceutical companies?

Mr Stuart—I am not sure I completely understand—

CHAIR—How does the broader community know? Is that a process where you seek input from consumers as well?

Mr Stuart—No, the MYEFO is a government budgetary announcement—in effect, in this case, a statement of intention. Consultation was with affected companies.

CHAIR—That is my question. So it is only with affected companies and not with consumers?

Mr Stuart—Peak industry bodies in this case were also consulted.

CHAIR—So it was peak industry bodies and the companies involved but no consumers?

Mr Stuart—That's right.

CHAIR—And the consumers first knew—besides the process through PABC, and we know the confidential process around that—on 19 January. Is that right?

Mr Stuart—No, on 2 November the MYEFO was published. It is a publicly available document.

CHAIR—But there is no formal consultation as part of that with consumers?

Mr Stuart—No.

CHAIR—They could write to you and say, 'We do not like it,' or, 'We love it,' or whatever, but they are not part of a formal process?

Mr Stuart—There is a consumer representative with the PBAC, and so they would have been part of that process, but in this case the overwhelming impact here is for the taxpayer and the company and so we consulted further with the companies and the company representatives.

CHAIR—I understand what you are saying about the overwhelming impact; however, a lot of consumers were here today saying, 'It potentially has an overwhelming impact on us too.' So that is my point—were they part of the process? I know that there is a consumer on PBAC; we have been through that. We have also been through the fact that that person is bound by a high degree of confidentiality.

Mr Learmonth—I think what we have been trying to make clear, though, is that the only impact of this is on the price we pay to companies.

CHAIR—I understand what you are trying to say. The point is that there are a whole lot of people out there who get a different message and have obviously got a different message.

Mr Learmonth—But not necessarily an accurate message.

CHAIR—The point is that in any consultation process that is when you enable people to get an accurate message.

Mr Learmonth—Sure.

CHAIR—Okay, I have taken us over three minutes. Thank you very much. You have taken on board plenty of homework. If we could get that as soon as you are able, that would be appreciated.

Mr Learmonth—We certainly will.

CHAIR—Thank you.

Committee adjourned at 4.03 pm