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SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Reference: National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

TUESDAY, 9 NOVEMBER 2010

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SENATE COMMUNITY AFFAIRS

LEGISLATION COMMITTEE

Tuesday, 9 November 2010

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

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

Senators in attendance: Senators Boyce, Carol Brown, Fierravanti-Wells, Moore, Siewert and Trood

Terms of reference for the inquiry:

To inquire into and report on:

National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010

WITNESSES

Committee met at 8.32 am

CHAIR (Senator Moore)—I declare open this public meeting. The committee is commencing its inquiry into the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010. I welcome representatives of the Generic Medicines Industry Association.

CROSS, Dr Martin, Chairman, Generic Medicines Industry Association Pty Ltd and Managing Director, Alphapharm Pty Ltd

ELLIS, Mr Robert, Board Member, Generic Medicines Industry Association Pty Ltd and General Manager Business Development, Sigma Pharmaceuticals Pty Ltd

LYNCH, Ms Kate, Chief Executive Officer, Generic Medicines Industry Association Pty Ltd

MILLICHAMP, Mr Roger, Board Member, Generic Medicines Industry Association Pty Ltd and Managing Director, Apotex Pty Ltd

CHAIR—I understand that information on parliamentary privilege and the protection of witnesses and evidence has been provided, and, if you have any questions or need help, the secretariat will be there for you. We have your submission and supplementary submission. I will invite you to make a short opening statement and then we will go into questions. We try to make it as open as possible and just have a discussion.

Dr Cross—Thank you very much for this opportunity to address your Senate committee. There is a saying that sometimes we contemplate the ants and the elephants are trundling past, and this is the case here. We have a major reform going ahead of the Pharmaceutical Benefits Scheme, and I do not think this has had the necessary scrutiny that it requires, given the major changes that will occur. The Pharmaceutical Benefits Scheme is covered very much in the National Medicines Policy. The fourth objective of the National Medicines Policy refers to a responsible and viable medicines industry. Should this reform progress, while the responsibility of the generics segment will be there, the viability of the segment will be seriously drawn into question.

I would like to go through the three major issues we have with this legislation. The first one questions the requirement for the legislation in the first place. What is this legislation fixing? The second one is: if you were going to put legislation forward, would this be the best legislation to do so? The last one concerns the way this legislation was put together in terms of the fairness of this legislation. Let me cover those three points one at a time. Firstly, in relation to this legislation, there is a good saying in life which is, 'If it isn't broken, don't try and fix it.' That is particularly true, I believe, for government. We need to understand what exactly this legislation is trying to fix. The PBS at the moment is declining in growth rate. The PBS at the moment is not going to increase as a percentage of GDP at less 0.7 per cent. The PBS at the moment is phenomenal value for money when we look at it relative to the other OECD countries, where we are in the lowest third of the costs of paying for pharmaceuticals. So there is no major problem with the PBS at the moment.

The last reforms which commenced in 2007 were the largest reforms since 1948 of the Pharmaceutical Benefits Scheme. These reforms have had a dramatic effect not only on our industry but also on the market and the potential savings running forward. The government's own forward estimates suggest that the growth rate of the PBS will decline to somewhere between 6.4 and 7.4 per cent by 2013. The 2007 reforms have already had a massive effect, plus the fact that these reforms were designed to play out over 10 years and we are only two years into these reforms. The reforms were designed to save $3 billion over that period of the forward estimates and already three independent assessments, including one of the government's own, say that they are going to save $6 billion—twice as effective as originally planned. Those were based on conservative estimates and our belief is that the actual savings will be in excess of that. The GMIA contends that the savings the government required are already coming to the government as a consequence of the 2007 reforms. This further reform is unnecessary. In fact, it is not sensible to build a reform upon a reform before you understand the trajectory that the initial reform is on. Should this be incorrect, the damage that will be done to this important industry will be significant.

This industry is critical to the health of the nation and the generic companies make medicines more affordable for patients, the government and the taxpayer. As a consequence, we are normally part of the solution not part of the problem. In addition, we contribute significantly to the exports of Australia, where we are part of the $4 billion of exports a year and the consequence of that is that we help the balance of payments. This is our leading export industry—more than cars, more than wine. It is really important that we make sure this industry is appropriately looked after and protected, and that we do not unnecessarily damage this industry. Looking at this legislation at the moment, it will unnecessarily damage this industry.

Secondly, should you decide that legislation is required and you want to do further reforms, would you do the sorts of reforms contained in this legislation? The answer, I think, is definitely no. There are serious shortcomings in the reforms as they are tabled at the moment. This legislation will cause some major issues. I do not have time today to go into all the issues, but let me cover two that are fairly significant: the supply of medicines and the area of administration. The supply of generic medicines will be fundamentally changed by this policy and it will become increasingly difficult to supply forward because a lot of the manufacture will disappear overseas and the supply chain will become much longer. In this whole area of supply, the legislation is going to cause difficulties. There are major transition points where the costs cut and there is no transition arrangement in place

Let me make this simple. I will give you the biggest example. On 1 April 2012 the price of the generic marketplace will be decreased by the government in a mandated 27½ per cent cut. It says 23 per cent but there are some products that are outside of that and cannot be cut, so we had to have a mandated 27½ per cent cut. Just imagine for a moment what that must mean as a company—all the companies are represented here—where the day after 1 April 27½ per cent of your products, on average, are cut. That is a massive impact which is almost impossible to cope with. Not only is it difficult for us but, as you will have seen from the submissions, it is also very difficult for other people like the Pharmacy Guild and the wholesalers. None of them want a product in their supply chain that the next day is worth 27½ per cent less. What will happen is that they will destock the supply chain and then on 1 April we will be asked to supply seven weeks of stock into the market. We are not going to be able to do that. There will be stock outs and patients will not get their essential medicines. That is a major problem with the current legislation.

Added onto that there is the assumption that, as the prices come down, all companies will be equal. All companies are not equal. Every company has a different cost of goods. One company may manufacture internally and have a very low cost of goods, another company may licence in. So if a product decreases by 50 per cent in cost for one company they might say, 'This is okay, we still have a market'. Another may withdraw their product from the market. When the product is withdrawn there is no guarantee who is going to step in to replace the lost volume. In addition to this the supply chain, as I have said, moves overseas. The supply chain becomes much longer. At the moment when we have a supply issue we can solve it very rapidly often within days or weeks. This new supply chain out to India, Eastern Europe and China will take months to resolve so, when we have a supply issue, we will not be able to resolve it. Finally, we have the area of pandemic supply. As our manufacturing is destroyed and the manufacturing disappears overseas should we have a pandemic and require the production of pharmaceuticals we are going to have a strategic issue in Australia. This is an important strategic issue that is not considered.

The other area I mentioned, and I only want to go through very briefly, is administration. I frankly do not know whether I am able within my company to meet the requirements of the administration load required by the new legislation. Should this legislation be rushed through at the speed it is I only have just about three weeks to go there and I still do not have details of exactly what I have to do. The devil is in the detail with this reform and there is no detail, so there are going to be major issues running forward on this legislation should it go forward at the rate and speed and without the lack of detail that there currently is.

The final area that I would like to look into is the process by which this legislation is put together. This is a highly irregular and inappropriate process. In effect the government have negotiated a secret negotiation on the memorandum of understanding with only one party to the exclusion of the other parties that are affected—not only ourselves but also the wholesalers. The problem with this is that we are actually the supplier of the lion's share of the generic marketplace. To negotiate an agreement with a minor party of this market is totally and utterly inappropriate and the consequence of that is, as is obvious, that when you do that you end up with extremely poor legislation.

In conclusion we contend that this legislation firstly is not required because it is not fixing anything. The 2007 reforms had a dramatic effect with huge layoffs and are already playing through. Further reform is not required and we believe the only reason for this reform at the moment is that the government would like to have some more cash in the budget. That is a not a good reason to potentially destroy the generic sector of the Australian market. The second reason is, if you decide and it is decided that the legislation is required, then you should at least ensure that you have a good piece of legislation handling the demand side as well as the supply side. Third, you should ensure that you have appropriate consultation with all the people affected.

So the GMIA would like to request the Senate not to pass this legislation, but instead to refer it so that there is the opportunity, firstly, to look at the impact of the 2007 reforms—what will they truly be delivering to the

nation and are these reforms even required, because the money is coming to the country already?—and, secondly, should the conclusion be that, yes, some reform is still required, for us to provide input into that reform. That is because we believe that there are much better ways of achieving more appropriate changes within the Pharmaceutical Benefits Scheme that will not destroy and damage this important sector.

CHAIR—Thank you, Dr Cross. Mr Ellis, Mr Millichamp or Ms Lynch, do you have any further comment you want to make at this stage?

Mr Ellis—I wholly support what Martin says. Being one of the two major manufacturers supplying the predominant volume to the PBS, I will reinforce very strongly that manufacturing in Australia is under extreme threat from this legislation.

CHAIR—I know Dr Cross's firm is Alpha—

Dr Cross—My firm is Alphapharm. Alphapharm delivers about one prescription in five to the benefits scheme in volume.

CHAIR—Mr Ellis, what is your firm?

Mr Ellis—Sigma Pharmaceuticals. Our input is the same as Alphapharm's, so between us we are very significant.

CHAIR—Mr Millichamp, are you representing a firm as well?

Mr Millichamp—I am representing Apotex.

Senator SIEWERT—I want to start on your third point first, Dr Cross: that the process has been irregular. I think you raised that point in another inquiry—I think it was the therapeutic groups inquiry. I am sorry; some of these inquiries run together. Your point was that an MOU had been signed with Medicines Australia and that you had not been consulted. When we asked the department about that, the department said that they had tried to talk to the generics but that the generics had not wanted to negotiate away from a fixed set of points—I am paraphrasing here because I do not have the *Hansard* in front of me. I thought we should start there because this has been going backwards and forwards. Could you detail what discussions you had with the department or with the government in this process?

Dr Cross—I would first like to make one point clear: there has been zero consultation with the GMIA on the MOU and on this legislation. I want to make that absolutely clear. Obviously there is always consultation between industry bodies and the government and the department. Unfortunately, I only became the chairman during May, so I need to defer to Kate as probably the most appropriate person to take us through the discussions that took place. But it is really important that the Senate understands that there was zero consultation on the MOU—there was no opportunity to consult and it was the same with the legislation. We were totally excluded.

Senator SIEWERT—That is over this specific MOU that was signed with Medicines Australia?

Dr Cross—You will have to ask Medicines Australia when the negotiations for the MOU started, but my understanding is that it was sometime around March and that it was negotiated over about three or four months before being finalised in the budget. But obviously we were not party to those negotiations.

Senator SIEWERT—Before you start, Ms Lynch, perhaps we should be really specific here. I am not making a judgment on whether it is appropriate that an MOU was signed directly with Medicines Australia, but if the government had decided to go with Medicines Australia—and maybe that is commercial-in-confidence—perhaps we can go back to the objects that the MOU was trying to achieve—were they discussed? Do you see the distinction I am trying to make? I can—

Senator CAROL BROWN—Reform of the PBS.

Senator SIEWERT—Yes, the objects were the reform of the PBS—further reforms beyond the 2007 reforms. Was there a process of talking to you? How did that roll out?

Ms Lynch—I think probably the best place to start in discussing the consultation would be with the request from the government to invite stakeholders to put in a review or precis of the impact of the 2007 reform. I think GMIA, as other stakeholders did, put a submission to the department—a review of the impact of the 2007 reforms. The GMIA's submission raised a number of concerns with the 2007 reforms and put forward an integrated package of amendments.

When looking at a policy analysis it is important to take a broad view of the impact of the policy. Once more, a change to a trigger in one place is going to have unintended consequences across the whole place. The

package put forward by GMiA looked at that in quite some depth. GMiA became aware subsequent to putting that submission to the department, which was early November 2009, that some of the overarching principles such as the government's commitment to the price disclosure policy were to remain in place. As a consequence of that GMiA, in a desire to stay engaged, contributed to policy amendments moving forward and then was in the unenviable position of needing to put suggestions forward. We continued to have the opportunity to put suggestions forward but we were unaware of where the mainstream debate was happening, which was clearly around the construction of the MOU.

In a vacuum we had an opportunity to put forward some suggestions, which we continued to do in good faith. But there was no opportunity to debate the merits of those particular suggestions because any policy from this needs to be considered in the context of the overarching reform or changes. It was not even a constructive dialogue. It was, 'Here are some suggestions that we think have good merit.' The response was, 'Well, we don't think they will work.' That was pretty much the response: 'They're just not going to work. Go back and think of some more.' Without the ability to know where the mainstream debate was happening, it was impossible to have a robust discussion and real input.

CHAIR—Ms Lynch, what do you mean by the 'mainstream debate'? My understanding is that there were discussions going on. I always worry about the term 'consultation' but, in terms of process, you were consulting and discussing with the government about ideas you had. The government was discussing with other groups ideas they had. What is this 'mainstream debate' argument?

Ms Lynch—The mainstream debate was clearly around the MOU and the bill. We became aware of the MOU on budget night. The bill was later tabled in parliament. We had no input into the actual reform.

CHAIR—The first you heard was on budget night? No-one discussed with you what had happened before budget night?

Ms Lynch—No. The MOU was signed roughly the week before the budget. The budget night was Tuesday so the MOU was signed about a week ahead of that. On the Friday prior to the budget I received a phone call from the department inviting the board to receive a briefing on what was to be announced on budget night. By that time it was a briefing. There was no opportunity for consultation by that point. It was due to be released to the public two days later.

Senator TROOD—Did you know the MOU was being investigated?

Ms Lynch—We knew there were discussions being held with other stakeholders.

Senator TROOD—Did you know it was going to end up in an MOU?

Ms Lynch—No. We had no idea of an MOU.

Senator TROOD—So you did not know that the discussions and negotiations that were taking place were going to end up in a MOU?

Ms Lynch—We had no idea.

Dr Cross—I will clarify this because I do have connections. I was aware early that there was a strong agreement being brokered between the government and Medicines Australia and made representations to also be involved but those representations did not go anywhere. The first time we officially knew there was more of a signed agreement was when it was published on the front page of the *Australian Financial Review* on about 4 May, from memory. Shortly after that we got a request, as Kate said, on something like 7 May to have a briefing and then it was published and we saw the full details of the MOU.

CHAIR—Did you take up that briefing?

Dr Cross—We did not take up the briefing, because we could wait 24 hours. Frankly, we did not want the department to be able to say, 'We had consulted with all parties prior to the publication.' There was zero consultation with us during the MOU or anything to do with this legislation.

Senator BOYCE—DoHA has a list of eight meeting dates that they had with you between November 2009 and April 2010 which they refer to as consultation with you. What happened there if it was not discussions around the MOU?

Mr Ellis—Roger, Kate and I were involved from the beginning of the process. From our first detailed submission of a package of proposals that would benefit the industry, the government and the taxpayer, any dialogue was initiated by us, with great effort. The other side did not engage us in this debate at all. All the initiation of debate was from our side.

CHAIR—Were you refused any meetings?

Mr Ellis—I will defer to Kate on that. I am not sure.

Ms Lynch—We continue to request meetings. Meetings were very difficult to come by.

CHAIR—Were you refused any meetings?

Dr Cross—I can speak personally as the new Managing Director at Alphapharm. I have been trying to meet with the Minister for Health and Ageing since I came in in January and I have still not had a meeting with the minister. I have made repeated representations because we are the largest single supplier of pharmaceuticals.

CHAIR—Have you met with the minister's office, Dr Cross?

Dr Cross—I have met with the minister's office. I have had one briefing with the minister's senior adviser.

Senator FIERRAVANTI-WELLS—I will put this in context if I can. How many millions of prescriptions are given out every year, Dr Cross?

Dr Cross—I do not have that figure, I am afraid.

Senator FIERRAVANTI-WELLS—What I am trying to understand is how many of those prescriptions are generic medicines. I would like to understand your market share as a percentage.

Dr Cross—Firstly, I can explain to you that this is an imperfect world for market share. The reason for that is that there is a commercial company called IMS that produces market share but neither Sigma nor Alphapharm supply in.

Senator FIERRAVANTI-WELLS—You said before that one in five prescriptions—

Dr Cross—Yes. That is for my company. Let us be clear, because we have managed to construct the market. Unfortunately, the government do not know the figure because they do not collect the prescriptions that go out under the co-pay arrangement. So the government have an imperfect view of the market here. The best view of the market that we currently have is based on a bottom-up constructed view of the market based on internal data from one of the member companies. Seventy-five per cent of the volume of the off-patent market is supplied by generic medicines companies.

Senator FIERRAVANTI-WELLS—In other words, you are the companies most affected by these reforms but you were not consulted.

Dr Cross—Absolutely.

Senator FIERRAVANTI-WELLS—And the agreement was entered into with an entity which, in effect, is a beneficiary, but you are the most directly affected and you were not consulted as part of the process. Do I understand Ms Lynch's evidence correctly that the government had an ongoing dialogue in relation to reform but not specifically in relation to an MOU?

Dr Cross—Or the legislation. Exactly right.

Senator SIEWERT—Can I clarify the percentages. It does my head in because I hear different figures all the time. How much of that 75 per cent is provided by members of Medicines Australia who are producing generics? I understand that they also produce generics.

Dr Cross—They do. Their originator products turn into generics when the patents go. They do 25 per cent of the volume.

Senator SIEWERT—Is that 25 per cent of the 75?

Dr Cross—No. That 75 per cent is the whole of the off-patent market, so they do 25 per cent of the market. Our members—not all our members because it is all the generic companies and we only cover, as the GMiA, 90 per cent of the generic market—have the lion's share. That 75 per cent is all the generic companies.

Senator CAROL BROWN—Is that volume or value?

Dr Cross—That is volume. By value it is 68 per cent for the generic companies and 32 per cent for the originator companies because their medicines are more expensive.

CHAIR—Dr Cross, can I ask this question on notice. You have an extraordinarily detailed submission but I did not find this data there. You have made the statement that the government has an imperfect database. We will follow up on that. Can we get on notice where those figures you just quoted us came from and how they are calculated so that we can then share them with all the people who are making claims to the contrary, to get

an agreed database. It will not be now—we do not have time—but that is something I am sure you can provide on notice.

Dr Cross—These figures are already in our submission.

CHAIR—I know they are, but your figures say one thing and other submitters say another. What I am trying to find out is where we can come to agreement. I am sure that is what Senator Fierravanti-Wells is questioning.

Senator BOYCE—Medicines Australia say that their members provide 67 per cent of the total prescriptions in Australia. Does that mean that you supply 33 per cent of total prescriptions?

Dr Cross—I am not sure, because it depends whether they are counting the medicines under the co-pay. This is the problem. The government's data is imperfect.

Senator BOYCE—They say they supply 67 per cent of the total number of prescriptions dispensed.

Dr Cross—We would have to take that question on notice.

Senator BOYCE—Thank you.

CHAIR—We will be putting the same question to others.

Ms Lynch—To add one quick point to that: irrespective of market share, the generic medicines sector is a strategically important sector. We offer checks and balances. Any policy reform should take account of the views of the generics sector.

CHAIR—Absolutely. I do not think that at any stage anyone has questioned that statement. I am sure we will hear it with hands on heart in other evidence. The way the system operates relies on the engagement of your sector, so I think it is important that that be acknowledged.

Senator CAROL BROWN—Have you read the department's submission?

Ms Lynch—Yes, I have.

Senator CAROL BROWN—Senator Boyce talked about a list of meeting dates that you had with officials and the minister. From my understanding of this process, the department entered into conversations with Medicines Australia and GMiA to talk about the reform of the PBS. What did you put forward in your discussions? It was not about the MOU; I understand the commercial-in-confidence aspects of that and I would not have thought that you would have been briefed on that. What were your thoughts on further reform?

Ms Lynch—The original submission in November was an integrated package of about 10 amendments. It was very clear that the government was not going in that direction, so when that message was received we then were in a situation of trying to tease out ad hoc reforms. There were a number of them. Some were about putting in place a market mechanism to provide incentive for a consumer to choose a generic medicine. There was a piece about protecting low-price medicines. There are some medicines on the PBS that are at a very low price, and when we have these repeated flat percentage price reductions these medicines are hit very hard by that. So there was a piece about that.

Senator CAROL BROWN—In the department's submission they said that your key ongoing proposal during the consultation period was that the patients should be made to pay more for off-patent medicines.

Ms Lynch—That was under the umbrella of providing a reason for the consumer to choose a generic medicine. At the moment, when the patient goes to purchase their medicine, there is not a lot of reason beyond: 'There is public benefit attached to me choosing a generic medicine.' Beyond that there is not a direct benefit to the patient. That particular proposal, which was one of an integrated package and which has been cited in the department's submission, mirrored what we already have: therapeutic group premiums, where a manufacturer may choose to put an additional price on the medicine which the consumer can choose. In all instances the consumer has an opportunity to avoid making that additional payment, so the patient's health is not jeopardised and access to the medicines is not jeopardised. In the bigger picture there are an array of proposals that were put forward, including that one.

Mr Ellis—The critical thing that we tried to talk to government seriously about was that the industry must have a volume driver. With this proposed legislation they have removed any potential for that. I can tell you from here that, as one of the major two manufacturers in Australia, we benchmark ourselves. We can manufacture in Australia and supply this market with medicines and compete with anyone in the world, including the Indian manufacturers, if we have the volume. I am quite happy to give you some examples, if you wish, of medicines that we can do that with.

Dr Cross—If I can be clear: in most parts of the world, as I said, the generic medicines industry is part of the solution, not part of the problem. We make expensive medicines much more affordable to the nation and also to the patients. So switching from the originator product rapidly over to the generic product saves a huge amount of money for patients and the nation. But there are not the proper drivers here in Australia to do that. So our generic substitution is much lower than many other nations. So where we should be looking on policy, first of all, is how we accelerate the switch from the originator. They have the whole of the market when the patent goes. So the more rapidly that can be switched, the more money the country can save. The MOU actually prevents the government, over the next five years, from negotiating ways forward to look to encourage the use of generic medicines. It does not make any sense.

Senator CAROL BROWN—I think you said you had 10 proposals. Is that right?

Ms Lynch—That was in November. It was an integrated package. Government made it clear that a number of those proposals were out of line, out of step with current government policy.

Dr Cross—We can obviously share those proposals.

Senator CAROL BROWN—Please do it on notice.

Senator TROOD—It seems to be common ground that the generics market is a modest section of the overall pharmaceuticals market in Australia, compared to some other countries. In fact, it could be considerably greater. That is my understanding of your position. In fact, it is the understanding of all submitters; is that right?

Dr Cross—I would say that is true.

Senator TROOD—You also say in your submission that the MOU and, consequently, the legislation precludes any expansion of the generics market. It focuses on the F2 formulas and drives down the prices of those formulas, which you may not much like, but that is a legitimate way of the PBS saving money, is it not?

Dr Cross—It is.

Senator TROOD—The part of it which seems to me to be unaddressed is why we may not increase the actual number of generic substitutes for medicines. The legislation and the MOU do not seem to provide for that. That is my understanding of your position. Is that correct?

Dr Cross—Again, this is the whole point. If you were looking to bring forward this legislation you would look to drive more substitution into generics because—

Senator TROOD—Sorry to cut you off; we do not have a lot of time. Perhaps you can tell the committee what you think the legislation may do to try to drive a greater use of generics.

Dr Cross—I can give you a simple policy that has been used in many parts of the world. You have compulsory substitution, except where the doctor marks the box. So you compulsorily substitute out of the originator brand. That has been very successful in many parts of the world in driving significant volume into the generic industry and saving a lot of money for both taxpayers and also patients.

Senator TROOD—That is still not in the interests of Medicines Australia?

Dr Cross—Absolutely not.

Senator TROOD—Why is that?

Dr Cross—Because they lose all their tail of products that they have had for many years. We have a social contract: join patents. Patents are given to protect the intellectual property for a period of time for the originator to make money. They make their money. The end of the social contract should mean that the product now gets commoditised. This is not happening in Australia and this is the big issue.

Senator BOYCE—That brand still has a prominence.

Dr Cross—Absolutely—

Senator BOYCE—and a view in the public—

Dr Cross—because it has 100 per cent of the market when it goes off patent. It is very difficult to take that 100 per cent away.

Senator TROOD—I do not know a lot about this market but, to me, mandatory substitution seems to be a considerable policy change in this context. Are there other things that one may do to substitute or encourage—

Dr Cross—Absolutely.

Senator TROOD—Can you tell the committee what else may—

Dr Cross—There has to be some signal to the patient that it is in their benefit and in the nation's benefit to use a generic product. There is no signal. There used to be brand price premiums that the originator products put on top of the co-pay, but the originator companies now very sensibly in the new world that they are in are taking away those brand price premiums so that they can maintain their volume. Every product where the product volume is maintained in the originator product post patent costs the nation money. All sensible countries accelerate the rate of substitution because, the more generics that are used, the more our industry can compete with other places in the world, the better our exports will be and our nation will save more money. But this policy does not address this issue whatsoever.

Senator FIERRAVANTI-WELLS—Can I just ask one question, coming at it from another angle. Is one consequence, arising out of this MOU—you mentioned the percentage share of the major pharmaceuticals that also have generic lines—that those generics, because they are tied in with major pharmaceutical companies that rule, then go on in this new scenario to be in a far better market position, in effect, to drive out of the market those that are the traditional generics, such as Alphapharm and others. In other words, you are saying that what you do not achieve in one way will be achieved through a different mechanism but ultimately will get to the point where the generic industry is considerably reduced so that the market is then shared by patented medicines and then medicines that are generic but associated with originator companies? Is that the gist of what you are saying?

Dr Cross—The market is dynamically changing. So, first of all, the products of the branded companies remain as branded products. Then the generics come in and bring in lower prices. But the branded companies are now working and blending more into the generic marketplace. They are using the power of the brand to also go into generics. For example, one of the branded companies is also the second-biggest supplier of generics in the marketplace. More and more of the branded companies are operating in the generic space. More and more of the branded companies are offering incentive off their protected products to discount and force use into their more expensive generics. So they are trading off. There are a lot of dynamics going on in the marketplace and—

CHAIR—Dr Cross, can you give us on notice information that shows that those generics are more expensive?

Dr Cross—Yes. Just to be clear, these are the off-patent original brands.

CHAIR—You just used the term in your evidence 'more expensive generics' and I want to get that clarified. It is not a term I have heard before.

Dr Cross—Just to be clear: these are the originator brands. When the patent goes, in effect, they are in the commoditised market.

CHAIR—But they are not generics?

Dr Cross—Well, if they are in the generic marketplace—no, they are originator brands.

CHAIR—This is confusing enough, Dr Cross, without confusing the definitional terms we have. This is really important.

Senator FIERRAVANTI-WELLS—Obviously, Dr Cross, you must feel very strongly to take these sort of ads out in yesterday's national press. They would not have been cheap.

CHAIR—We have actually taken them as a submission.

Senator FIERRAVANTI-WELLS—It is part of their submission.

CHAIR—One more question, Senator Trood, and then we will have to wrap up.

Senator TROOD—Perhaps you could just explain something to me that I find rather confusing. On page 13 of your supplementary submission you refer to some anomalies. You refer to three medicines which are included in the F2 formulary, which, as I understand it, are worth $250 million. I am just not clear. These are in the F2. I would have thought that, because they are in the F2, they would be subject to this process of reduction—the price drivers, the lowering of the price. Is that not right? On page 13 of your supplementary submission, there is a heading 'The bill contains many anomalies and cannot be implemented.'

Mr Ellis—The fundamental flaw here is that these schedule 5 products, as they are referred to, are still patented products and therefore there is no discounting. Their value is affecting the calculation. Therefore, this 27½ per cent that Martin referred to, relative to the 23 per cent, is in fact the direct result of that: that there are

products that, because of the old regulations, were included in the formulary but are still on patent, so there is no discount. So they are artificially affecting the outcome.

Senator TROOD—So you are saying that they will distort the perception of the value of the market.

Mr Ellis—They distort the results in terms of the calculation of this mandated 23 per cent reduction in price.

Senator TROOD—So they will distort the market. So, since they are in patent, they ought not to be in the F2—

Mr Ellis—Absolutely.

Senator BOYCE—Or F2 should stay split. Is that what you are saying?

Mr Ellis—Also, it focuses on one of the direct weaknesses in this proposed legislation, because this legislation prevents the creation of therapeutic groups. It goes—

CHAIR—For a period of time.

Mr Ellis—Yes. It also prevents the introduction of any price driver, which we are talking about to create a volume product.

Dr Cross—Could I make one other point as well. We are not even sure whether the mandated 23 per cent cut, which in reality will be a mandated 27½ per cent cut, is illegal from a Trade Practices Act perspective. How can a government just decide on a mandated cut in a market which does not have any arbitration or anything along those lines? So this is something else we believe should be looked into in terms of this cut. This cut has to occur. It is mandated at this level, and we believe this is primarily so that the cost saving can be put into the forward estimates.

CHAIR—This is the cost cut in 2012?

Dr Cross—This is 1 April 2012.

CHAIR—I just wanted to check that.

Dr Cross—There are also mandated cuts in February 2011 of two per cent and five per cent.

Senator TROOD—The MOU has been revised since the original was signed, largely in relation to timing. I note that the Pharmacy Guild's supplementary submission focuses on dates. Do you have a view on the recommendations of the Pharmacy Guild in relation to dates?

Dr Cross—First of all, we contend again that we need to check that this legislation is required. Should the legislation go through, it is being rushed through with unseemly haste given the fact that full consultation has not occurred, there is no detail of how some of the transitions are going to be handled and there are no details of the full administration that is required. Yet this legislation is supposed to go in and be enforced from the beginning of December. The time is—

Senator TROOD—There is a working party, as I understand it. Are you on the working party, Dr Cross?

Dr Cross—There is a working party, but we have been going to briefings. Because we have not been involved in the legislation, there has been no real consultation with the GMiA. Just to be clear, we have been turning up to the working party to listen to what the working party has to say, and there is a lot of detail that has not been covered.

CHAIR—Dr Cross, there are a number of questions that I know people have, but it is a process we are going through. I have two questions to put on notice, and there will be others. We will need the answers to these very quickly, but I have no doubt that you are already focused on the process. One thing is about the statement in the department's submission that talks about the cost of generic medicines in Australia, makes comparison with other countries and indicates that we are paying more. Your submission says that we are paying more for patent medicines than we need to. The department's submission says that we are paying higher than the international market price on generics. I would like to get something back. You do not address that in your submission.

Dr Cross—Can—

CHAIR—No, we have not got time now. If we can have that on—

Dr Cross—My comment would be that that is exactly why we had the 2007 reforms, so that will not be the case running forward. It is a transition we are running.

CHAIR—I would like to have some data, because I would imagine that the examples are extreme in terms of making a point.

Dr Cross—That is why we had the 2007 reforms.

CHAIR—We would like that in terms of looking at that process. The other question is about the international market and also your five companies who are members of GMiA. How many of those are international companies and how many are purely domestic? I would also like the volume of their manufacture, which is a very important issue. That is for the international market as opposed to the domestic market on that basis.

Dr Cross—So do you want to know how much of it is exported from the manufacturing institutions?

CHAIR—From the manufacture and distribution. My understanding is that most of the companies are international companies and linked in that way. I want to have that in terms of the five members.

Dr Cross—Some but not all.

CHAIR—We need to have that confirmed. In terms of process, could we have a look at the volume of market and also that process in terms of international manufacturing and export as opposed to domestic market.

Dr Cross—Yes.

Senator BOYCE—I also ask on notice that you tell us what percentage of the PBS medicines that your members sell in Australia are manufactured in Australia, with as much detail as you would like to give us there.

Dr Cross—Yes.

CHAIR—Thank you very much, as always. I know that you have gone to extreme effort in providing submissions and information. If there is anything you wish to add, please be in touch. If possible, we would like to have the answers to the questions on notice by the end of the week.

Dr Cross—Okay; no problem.

[9.20 am]

ARMSTRONG, Mr Stephen, National Manager, Economic Analysis and e-Health, The Pharmacy Guild of Australia

RILEY, Ms Toni, Chair, Health Economics Committee, The Pharmacy Guild of Australia

CHAIR—Welcome. I believe you are experienced in this process, but I will go through the opening statement. You have information on parliamentary privilege and the protection of witnesses. We have your submission and your supplementary submission, I believe. I now invite you to make an opening statement and then we will go to questions from the senators.

Ms Riley—I have a prepared opening statement and I will read some, though not all, of it.

CHAIR—Would you like to table it?

Ms Riley—I will table a copy.

CHAIR—If it is information you want us to have, just table it and focus on what you want to do.

Ms Riley—Apropos the evidence we have just heard, it is probably a good idea to just focus on some important points.

CHAIR—That is the idea—that we share the knowledge; that would be great.

Ms Riley—As you are aware from our submission, the guild is seeking some small but important changes to the current bill to ensure a smooth transmission to the new arrangements. The guild's proposed changes would have no effect on the level of savings or the timing of the achievement of these savings. The bill was introduced to parliament in 2010 and was delayed by referral to the committee and then by election. The original bill had a starting date of 1 October 2010 for changes to price disclosure. Sensibly, the version of the bill that was introduced to parliament on 29 September had been amended, compared with the June version, to delay the 1 October 2010 change for price disclosure until 1 December 2010. I guess that was written with the expectation that it would be passed at the September sittings, and that was evident by the use of 11 October as a reference point for deciding the drugs which will be subject to price reductions on 1 February 2011—there are an awful lot of dates. Had the bill been passed in the September sitting, it would have allowed a two-month notice period to the industry, which would have allowed adequate time for the necessary communications and market adjustment and for minimising the possibility of errors in procedures and data collection.

As you would well know, the reporting date for this inquiry is 16 November. That will now mean that the bill cannot be considered by the parliament until one of the latest sittings in November. In recognition of this, we feel it is important that the bill has some further amendments, and the guild proposes a couple of changes: firstly, that the proposed date of 1 December as a starting date for price disclosure be delayed until 1 February 2011, and, secondly, to ensure that the level and timing of government savings are not affected by the first change, that the duration of the data collection period for the 1 February 2011 round of price disclosures be further reduced, from 10 months to eight months. This would still allow for the original planning of the price reduction on 1 April 2012. We believe these changes would have no impact on the savings that have been booked in already in the forward estimates. The 1 February price reductions would occur as scheduled on the same range of drugs. The price reductions on 1 April are guaranteed by this bill to average at least 23 per cent, and the timing and scope of these would not be affected.

Our proposal also addresses some serious risks that exist in relation to the expansion of the price disclosure policy. The first risk relates to the preparedness of the manufacturers—and I think we have heard about that from GMiA, to some extent—for the very large increase in data management being brought about by these changes. The top four members of GMiA will be required to start disclosing on approximately 975 individual products as a result of this bill. A conservative assumption would be that each of these companies has accounts with about 1,500 pharmacies that order at least once per month. This represents close to 1½ million pieces of sales information each month that need to be managed and reported by these four companies alone. That is before accounting for any extra complexities such as product returns, bonus stocks and bundled deals. All of those things have to be included in the reported figures.

If the bill is passed in late November these companies will need to have systems, procedures and staff in place to manage this workload within a few days of the official notification and also in the lead-up to the Christmas and New Year period, keeping in mind that December is an extremely busy prescription month and of course an extremely busy retail month for pharmacies in particular. We feel it would be fraught with danger

and inevitably lead to mistakes in data and, ultimately, calculations that do not correctly match the market situation. I quote from Spirit Pharmaceuticals, a small Australian generics company who are not a member of GMiA. They say in their submission that their data collection systems:

> … are manual, the pricing structures complex and the collection and reporting of data represents a disproportionately high administrative burden related to the value of the product reported. We are reliant on timely, and correct, reporting from third parties in many instances and the rapid expansion of this requirement will undoubtedly lead to reduced reliability in the data.

As I mentioned earlier, a second problem we addressed in our submission was the risk of disruption to supply over the Christmas-New Year period. We expect that the bill will result in a rethink amongst many of the generic companies of marketing strategies and offers to pharmacies; thus community pharmacy owners and managers could potentially be faced with a rapidly changing purchasing environment and may suddenly face a deterioration in margins if they do not react immediately. It could involve purchases being delayed, switched to different suppliers, and putting this kind of market upheaval on pharmacies at their busiest period of the year—and not only busy in retail; it is, as you would know from PBS figures, the busiest prescription month of the year—could create significant transition risks, which is not necessary to meet the objectives of the reforms.

We understand that Medicines Australia do not support our views about the proposed changes. In contrast to the 1½ million pieces of complex sales data that will need to be managed, as I mentioned, by the four top GMiA companies, the four top Medicines Australia members, including their generic subsidiaries, will need to cope with a lot fewer—little more than 5,000 to 10,000 pieces of information. This is because they have a much smaller range of products affected and significantly fewer customers because the majority of their sales go through the three big wholesalers. Also, they generally do not offer trading terms to pharmacy. The data they need to handle will be far less complex than that of the GMiA members and they will not be exposed to the short-term supply chain upheaval.

Medicines Australia have suggested that reducing the data period from 10 months to eight months will impede the ability to obtain the necessary amount of data for the full market based assessment of what discounting is occurring. We believe this concern is unfounded. There are two groups of drugs being brought into price disclosure for this round. The first group are 99 drugs for which there has been a highly competitive generics market since prior to October 2006. It is clearly a stable market, and 10 months versus eight months will not make much difference. The second group are drugs which have had two or more manufacturers before August 2006 but have not had any new manufacturers list new brands since then. These drugs also are obviously a stable market, so shortening the period should not make any difference to them either.

It would create far greater uncertainty to collect data during December and January when the market is likely to be temporarily unstable following the passing of the bill and the companies involved may well be ill prepared for the change in processes and workload. A longer data period is only necessary for drugs that have just opened up to generic competition, in which case the market will take up to 12 months to establish and settle down. We do not have any drugs that fit that description at this stage entering into the price disclosure changes.

In closing, the guild do support the reforms included in the bill and the MOU and we do request your consideration of these simple, savings-neutral changes to the bill to ensure a smooth transition to the new arrangements and the accuracy and integrity of the data that will be provided to the Department of Health and Ageing.

CHAIR—Thank you, Ms Riley. Mr Armstrong, do you have anything to add?

Mr Armstrong—No.

CHAIR—I am just making sure that the batting order is correct. Now for questions.

Senator BOYCE—Yes, and if I could clarify a couple of things. You mentioned 975 new price disclosure items. The GMiA submission talks about 1,600 items. Can you explain that discrepancy?

Mr Armstrong—No, I am sorry but I do not know the difference there. Certainly the analysis that we have done based on the top four companies that are members of the GMiA against the PBS schedule indicates 975, but I would be happy to provide that information.

Senator BOYCE—Yes, if you look at page 79 of the GMiA submission you see they are saying it goes from 160 to 1,600.

CHAIR—Thank you, Mr Armstrong. I note that GMiA are still with us and I have seen them taking down notes, so if we could add that to the list of things for clarification.

Ms Riley—If I could add something to that, I think the difference could well be in the fact that we have only picked the top four GMiA companies. There are significantly more than four. So that would be the total number of products involved. We will clarify it.

Senator BOYCE—If you have picked the top four and it is almost double you wonder about the others.

Senator FIERRAVANTI-WELLS—There is a big difference as to the 1,600.

Senator BOYCE—Certainly. Will Pharmacy Guild members be financially affected by this bill and by the conditions of the MOU?

Ms Riley—Naturally when trading terms change there will be some financial changes for community pharmacy, so there will be some disadvantage with decreasing prices and so decreasing margins. They will certainly affect community pharmacists.

Senator BOYCE—So their margins will be affected and their profits will be affected?

Ms Riley—Yes.

Senator BOYCE—Significantly?

Ms Riley—I cannot give you total figures. Stephen might have indicators.

Mr Armstrong—Certainly over time they will be. The arrangements for the fifth guild-government agreement, or the Fifth Community Pharmacy Agreement, were negotiated in parallel with the arrangements that were negotiated with Medicines Australia. So to some extent the effect has been able to be taken into account, but of course those agreement negotiations resulted in a billion dollars worth of savings that are in addition to the savings from these reforms.

Senator BOYCE—But a lot of those savings will come from the drug manufacturers and wholesalers, will they not?

Mr Armstrong—Not the savings from our agreement but the savings from these reforms.

Senator BOYCE—I am sorry; I am talking in terms of the MOU.

Mr Armstrong—Yes, some will but, with it being at the end of the supply chain, pharmacy has to live with what it is dealt in terms of having to buy product at a particular price, and the reimbursement price is set by government. So there is limited opportunity for pharmacies if margins are squeezed to be able to pass it on to consumers.

Senator BOYCE—Nevertheless the Pharmacy Guild does not oppose this legislation, so I am assuming that the financial effect on your members is not significant.

Ms Riley—We certainly do not oppose these changes and we realise that they are necessary changes for the sustainability of the PBS, as we know and appreciate. But the impact on community pharmacy is not going to be on day one. There are going to be some small impacts, like the two per cent and five per cent price decreases in the formularies in February. But the reality is the other impacts are down the track and we have got time to prepare and we have got time to change the way we do business and the way we provide our services to the community, so there is a period of adaptation that community pharmacy is going to definitely have to undertake.

Senator BOYCE—I might put a few more questions on notice there. I note that a number of times in your submission you have made the point that you would vigorously oppose any further changes to the PBS pricing arrangements that might be considered in the future. Would you tell me what your concerns are and what you perceive the direction that concerns you that much to be?

Ms Riley—The concerns are around the decreasing prices of the medicines—the generic medicines—that we will be dispensing as each further round of price disclosure goes on. Historically they are going down and down in price, so consequently that is squeezing margins in community pharmacy. Our costs do not change and our needs to practise in an appropriate manner do not change. We have decreasing prices, decreasing margins and increasing costs. There is a balance somewhere along the line where they are going to cross.

Senator BOYCE—As you have pointed out with the pharmaceutical agreement and the like, there have been some compensatory moves made for pharmacies. So you are concerned they would not be offered in the future?

Ms Riley—We would hope that that would be offered in the future, but we have only agreement to June 2015. It would be our expectation, depending on the environment, that we would be negotiating on ongoing compensation in the future in the next agreement.

Mr Armstrong—This MOU ends one year before our agreement.

CHAIR—And, Ms Riley, that has been a standard practice of negotiation with governments of all flavours for the last many years?

Ms Riley—Yes.

Senator BOYCE—One of the comments of the GMiA was that if onshore manufacturing is affected such that it moves offshore there would be significant problems with the supply chain of generics to keep the market competitive. What is the Pharmacy Guild's view on that?

Ms Riley—Obviously we do not want to lose an Australian industry, for one, but the reality is that in the past we have had some examples of offshore generics being in very difficult supply for long periods of time.

Senator BOYCE—So that has happened in the past?

Ms Riley—It has happened in the past, yes.

Senator BOYCE—Are you able to think of any examples that you could give us?

Ms Riley—I will give those to you on notice, I think; there are a couple that come to mind but I would need to be 100 per cent sure of my facts before I put all that on paper.

Senator BOYCE—Yes, medicines that are not available for perhaps months.

Ms Riley—Okay.

Senator BOYCE—Thank you.

Senator FIERRAVANTI-WELLS—Previously you heard evidence in relation to the reform process. Were you consulted at all in relation to the MOU?

Ms Riley—We were aware that the MOU was being negotiated with Medicines Australia.

Senator FIERRAVANTI-WELLS—When did you first become aware?

Ms Riley—During our negotiations for the Fifth Community Pharmacy Agreement.

Senator FIERRAVANTI-WELLS—Can you set a time on that?

Ms Riley—That would have been in November-December last year. I cannot tell you the exact dates. But we were certainly aware of it well before then.

Senator FIERRAVANTI-WELLS—You were aware but you were not asked to comment in relation to the MOU?

Ms Riley—No, and we did not expect that.

Senator FIERRAVANTI-WELLS—And on the effect of it?

Ms Riley—No, we did not expect that.

Senator FIERRAVANTI-WELLS—You heard Ms Lynch make comments about requests by the Department of Health and Ageing in relation to the effect of consultations about ongoing reform of the PBS. Are you part of that process or were you asked for your views in a general sense in relation to reform of the PBS?

Ms Riley—Yes, we were. The health minister was to report in December on the effects of the PBS reforms. Prior to that report the minister did ask for submissions from interested parties. We certainly made a submission as to that. I presume, from listening to Ms Lynch, that was what she was talking about when she was talking about their submission as well, because we certainly put in a submission at the same time.

Senator FIERRAVANTI-WELLS—But part of that reform did not disclose or did not reveal the potential of an MOU and you only became aware of it simply because of your position in relation to what you were doing as part of the pharmacy agreement?

Ms Riley—Correct.

Senator TROOD—Ms Riley, there seems to be, at least in the government's submission and indeed a couple of others, supreme confidence that the administrative issues that arise as a result of this quite significant change in policy are trivial and can be overcome. Do you agree with that position?

Ms Riley—Not working with the manufacturers I could not be totally correct or true in what I say. But I would believe there would be significant reporting requirements. Just from hearing of the amount of reporting that was required for the first round of PBS reforms, I would imagine there will be an enormous amount of administrative work—

Senator TROOD—So it is not a simple or straightforward matter in your view?

Ms Riley—I would not believe so.

CHAIR—Senator, I am going to pull you up because I think the adjective 'trivial' did not appear in the government's submission—and there is your second statement about 'can be overcome'.

Senator TROOD—That is my word, Chair, and I am happy to own it. The argument seems to be that, because there has been price disclosure arrangements in place since 2007, there are some principles in place and all that needs to be done is to extend them to a wider range of products. In other words, the foundations for the administrative reforms are there already and all you have to do is extend them. Are you persuaded by that argument?

Ms Riley—If you say it quickly it sounds easy, but I think the reality is that not all the generic suppliers have been involved in price disclosure to this stage. There are some new entrants to the price disclosure market. Because such a large number of products are going to be involved in this price disclosure cycle, forever, there is a significant incline in the work that needs to be done by virtually everybody over this period of time. It would be my expectation that this is going to be a significant impost on the participants.

Senator TROOD—And somebody has to do the calculation, presumably, so it might take a little longer to do 900 products or items than it takes for 162. Would that be a fair statement?

Ms Riley—Absolutely. I do believe that the government has made consideration for that, though. They have mentioned in the MOU how that would be done. I do not think they are planning on continuing on the way they are.

Senator TROOD—They may have plans, but they do not seem to have talked to the people who are going to be most affected. I am not sure they fully understand the nature of the problem. You have alluded to that problem. A similar question seems to arise with regard to continuity of supply. You have mentioned this in your submissions. Do I take it this is a concern that you have about this?

Ms Riley—Absolutely.

Senator TROOD—There is this problem about costs that change at particular arbitrary dates, but that is the way price disclosure obviously operates. How do you and your members see this problem in relation to the continuity of supply?

Ms Riley—We are the last point in the supply chain, as you would well know. We are the link between the wholesaler, or the manufacturer, and the consumer. As a community pharmacist, somebody comes in with a prescription and you need to be able to dispense that and give it to them at the time they need it. Usually that is when they come into the pharmacy. If we are unable to order and receive stock in our normal routine manner, that creates quite a problem in community pharmacy. The plan for this to happen on 1 December, at the busiest time for dispensing in the year, is of concern. Our members know that this is in the wind, as do all the pharmaceutical manufacturers, but nobody has really got any definitive times, dates or sign-offs on anything at this stage, so there is an element of wait and see what happens. Consequently the preparedness is the big issue for us.

Senator TROOD—The Medicines Australia submission says that one of the great virtues of this arrangement is that it provides a degree of certainty about the market. Do you agree with that proposition?

Ms Riley—It provides a degree of certainty about the market for the future; it does not provide it at the start. I do not disagree with the fact that one of the statements in the MOU is that there will be no further change to pricing structures in that period of time to 2014. It is a really good thing for the industry and pharmacy and the community that there will not be disruptions in that period, because it does create a great deal of anxiety and uncertainty especially for pharmacists, who have a lot of money invested in the industry. If we believe that there are going to be major, sweeping reforms popping up out of the woodwork that we are not involved in, it does create a lot of anxiety and uncertainty, whereas this gives us that period of time where we will not have that.

Senator TROOD—But these are rolling changes?

Ms Riley—They are rolling changes, but you know when they are and what is involved. To have another completely new kind of PBS reform come in out of the blue—the very first round of PBS reforms in 2007 came in just after we had signed the fourth agreement. We had to go through another lot of negotiations. It created a lot of—

Senator TROOD—I am sorry for interrupting—and the chair is obviously keen to move on—

CHAIR—After 35 minutes, Senator.

Senator TROOD—but this is precisely the point. Your submission points to the fact that the 2007 reforms had barely begun.

Ms Riley—They had barely scratched the surface; that is right.

Senator TROOD—Your submission also provides information about the impact, already, of these reforms, which is far greater than the proposed or expected recovery from them, at $3 billion. The three studies that have been done provide somewhere between $5 billion and $7 billion in extra—

Ms Riley—That is right.

Senator TROOD—Doesn't that suggest to you—it suggests to me, and perhaps you can correct me if I am wrong—that these reforms are likely to have a far greater impact than originally anticipated?

Ms Riley—I will defer to Stephen on this one.

Mr Armstrong—The new reforms are building on the same framework. So they expand and essentially accelerate the process of price disclosure, and there is an additional mandatory cut on 1 February next year. The arrangements were negotiated and able to be taken into account in our agreement negotiations. If that were not the case, I do not think we would be supporting the arrangements the way we are. But they were able to be taken into account, so there was a redirection of some funds back into that agreement in recognition of the direct flow-on effect of these changes on pharmacy mark-ups, which are directly affected by the formula that makes up the reimbursed price. As Toni has alluded to, we believe that, if these arrangements were not going forward, we would not have any certainty that something else would not be forced upon us in the middle of an agreement, and we would have to go through a whole process of uncertainty for the industry and our members.

Senator TROOD—Thank you.

Senator CAROL BROWN—To continue on from what Mr Armstrong said, these changes that we have before us are an extension of the current scheme. When they were introduced—they came in, I think, in 2008—what was the experience of pharmacies? How did they cope?

Ms Riley—We had a longer notice period, obviously, so we had time to prepare for some of the significant changes that we were going to experience in the value of our dispensary inventories. One of the big concerns for pharmacies at the time of the first mandatory price reductions was the instant devaluation of the stock on our shelves. Consequently, as you would not be surprised to hear, people did not have a lot of stock on their dispensary shelves. On day 1-plus—the day after everything—the prices decreased and the wholesalers were swamped with orders. There were not major impacts on stock supply at that stage, but there was some stock that was not available for a short period of time because the manufacturers and wholesalers, of course, were in the same position as us.

Senator CAROL BROWN—But there was not any major impact?

Ms Riley—There was a reasonable impact. You would not call it a blip on the horizon. It certainly had an impact on community pharmacy; it had an impact on supply. But we did have time to prepare for it, whereas we have a lot less time this time.

Senator CAROL BROWN—And your members would be, obviously, familiar with the scheme and price disclosure—

Ms Riley—They should be.

Senator CAROL BROWN—because it is an extension of the current scheme. I want to ask about the awareness campaign that was run when the 2007 reforms were first made. Are you aware of the awareness campaign on generics?

Ms Riley—On generics? Yes.

Senator CAROL BROWN—Do you have any information about how successful that was?

Ms Riley—Since that period of time, the generic substitution has increased somewhat. I think it has increased six per cent.

Mr Armstrong—It has increased six to eight per cent over the last year and a half.

Senator CAROL BROWN—From?

Mr Armstrong—From high 60s to 75 per cent.

Senator CAROL BROWN—So it is quite worth while.

Ms Riley—Absolutely.

Senator CAROL BROWN—I understand there is going to be another awareness campaign. Are you aware of that?

Ms Riley—I am not aware of it, but that does not mean there will not be.

Senator CAROL BROWN—I will ask the department.

Ms Riley—I personally believe it was a very worthwhile campaign. For many years, Community Pharmacy have been offering people a less expensive option when they can. There has been a rapid acceleration in the understanding by the community of what we are talking about, and there is an expectation that, if they have an opportunity to pay less, they will be in that game.

CHAIR—Thank you very much. If there is anything you want to add, we need answers by the end of the week. We appreciate the ongoing evidence from the Pharmacy Guild.

Ms Riley—Thank you.

Mr Armstrong—Thank you.

[9.51 am]

DELAAT, Mr William Louis, Chairman, Medicines Australia

ORR, Ms Jane, Managing Director, MSD Australia and New Zealand

SHAW, Dr Brendan, Chief Executive, Medicines Australia

VERMEER, Mr Peter, Director, Corporate Affairs and Market Access, Eli Lilly Australia

WATERHOUSE, Ms Deborah, General Manager, GlaxoSmithKline Australia and New Zealand

CHAIR—Welcome. You have information on parliamentary privilege and protection of witnesses and evidence. We have your submission and your supplementary submission. We seem to have quite a few supplementary submissions to this inquiry. I invite any or all of you to make an opening statement, and then we will go to questions.

Mr Delaat—We thank you all very much for the opportunity to appear before the committee on behalf of Australia's medicines industry. I will make some opening comments. The PBS is a critically important component of our healthcare system. A financially sustainable PBS is in the long-term interests of Australian patients, taxpayers and industry. Medicines Australia members take seriously our role with government as co-stewards of the PBS. Medicines Australia's 50 member companies together manufacture about 86 per cent of all PBS prescription medicines. I know that figure has been questioned, and I am happy to take questions on that later on. Importantly, they also represent—again, this is a contentious figure—60 per cent, almost two thirds, of the cost to government of generic medicines sold at present.

Consistent with previous PBS reforms negotiated with industry and which now appear to be widely endorsed, this bill, firstly, benefits patients through the provision of cheaper prescriptions whilst ensuring they continue to have access to quality safe and effective new medicines subsidised by the PBS. Secondly, this bill enables the Australian government to be a more informed purchaser. It will deliver savings to government in the order of $1.9 billion by providing greater transparency and access to information so government can capture its fair share of discounting already occurring in the generic medicines market. Thirdly, the bill benefits the pharmaceutical industry because it provides policy stability and certainty for the next 3½ years—that is, until June 2014.

Medicines Australia has provided two submissions to this inquiry. I will not repeat all the points in them, suffice it to say that, in the submissions, we have highlighted why on any calculation Medicines Australia is well placed to comment on the impacts of the bill on the pharmaceutical industry. For many decades, the innovative medicines industry has worked collaboratively and constructively with successive Australian governments to ensure that Australians can have access to pharmaceutical benefits in a timely, affordable and universal way under the Pharmaceutical Benefits Scheme.

Faced with significant pressures on the PBS, which were compounded by the unprecedented global financial crisis, the industry decided to work constructively with the Australian government. I say 'constructively'. Negotiations were nonetheless difficult, lengthy and bound by budget confidentiality. Ultimately, a position was arrived at which was acceptable to all in the negotiations. The final result set a new precedent: a memorandum of understanding; an exchange of guaranteed savings measures, bankable over the forward estimates, for further PBS process improvements; and an explicit period of policy certainty.

We recognise that there are several longstanding and recurrent MOUs and agreements between government and other industries and parts of the healthcare system. Stability and certainty are common goals in all of those. This MOU, or medicines agreement, is an important step forward in the continued future management of a significant part of health care—the PBS. This year's budget papers show that the PBS will grow by an average of 2.1 per cent over the next four years in real terms, which is almost identical to the government's overall spending growth target of two per cent per annum. These figures incorporate the impact of the MOU and illustrate why the MOU is so important in ensuring that the PBS remains sustainable.

We would also like to acknowledge the former coalition government for its pioneering reforms of the PBS, as these paved the way for us to reach the current MOU. In 2007, the former Australian government, with Tony Abbott as health minister, fundamentally restructured the market for medicines in Australia to begin to drive savings in an inefficient, off-patent medicines market while ensuring that patients still maintained access to new and innovative medicines. The provisions contained within the MOU are entirely consistent with, and

build upon, the set of PBS reforms passed by the Australian parliament in 2007. As the Senate committee which examined those reforms in 2007 said:

> Consumers anticipate a fair price for PBS medicines, whether the price is paid by the individual consumer for medicines below the general patient co-payment or by Australian taxpayers through PBS reimbursement to pharmacists.

Like the 2007 reforms the 2010 bill explicitly recognises that discounting is occurring in the generics or off-patent medicines market. Despite the 2007 reforms, Australians are still paying almost the highest prices of OECD member countries for generic medicines while, by international standards, they pay amongst the least for innovative, new medicines. This bill is fair and equitable because, through thoroughly transparent price disclosure, the Australian government will harness the competition that is already occurring in the generics market and get better value from subsidising those medicines.

It will be the Medicines Australia member companies that will bear a large part of those savings. These savings in turn will create the financial capacity and policy stability that innovative pharmaceutical companies need to continue investing in and listing new medicines in Australia. The bill, which gives effect to the savings measures contained in the MOU, will help ensure that Australians continue to operate in a world-leading health system characterised by affordable, timely and universal access to new medicines. The MOU and the bill now before you benefit Australian patients, consumers and taxpayers, which is why it is supported, as you know, by the Pharmacy Guild of Australia, the National Prescribing Service, Breast Cancer Network Australia , the Consumer Health Forum of Australia and the Department of Health and Ageing. Even though many of our members will be financially impacted by the bill because of their strong presence in the generics market, they too support the bill. They recognise that there are considerable growth opportunities in the generics market and that ongoing financial sustainability of the PBS is critical to the success of all in the pharmaceutical industry—30 per cent of the PBS will come off-patent over the next 10 years.

The bill in its current form benefits all Australians because the outcome for government is a financially sustainable PBS through lower priced generic medicines. The outcome for industry is business certainty and the outcome for Australian patients is cheaper medicines and the very real prospect of earlier access to new and innovative medicines that improve lives and livelihoods. It is an appropriate step forward.

Medicines Australia and our member companies have provided many briefings to members of parliament on the MOU and the supporting legislation. We recognise the parliament's interest and bipartisan commitment to the PBS. We would like to thank everyone who has met with us over the last six months. Medicines Australia respectfully requests that the parliament pass the bill in its current form before the end of the spring 2010 sittings. Representatives from Medicines Australia companies are here with me today. I call on them to make very brief statements in support of the bill. First I call on Peter Vermeer.

Mr Vermeer—I would also like to thank the committee on behalf of Eli Lilly Australia for the opportunity to appear. Eli Lilly and Company has been providing the world with new medicines for 130 years. Lilly pioneered the production of insulin in the 1920s—a revolution in the treatment of diabetes that has since saved countless lives around the globe. Today we provide medicines to treat lung cancer, bipolar disorder, type 2 diabetes, depression and osteoporosis, among others. Eli Lilly Australia supports the memorandum of understanding and supports the National Health Amendment (Pharmaceutical Benefits Scheme) Bill.

The principal benefit in the MOU for Lilly is the certainty it provides in pricing for F1 on-patent medicines. This certainty is vital for Lilly and its more than 500 employees in Australia. The business environment we face is difficult. Four of Lilly's top seven medicines face patent expiration in a two-year period from 2011 to 2013. These expirations account for fully two-thirds of Lilly Australia's revenue. We have skin in the game. Pricing certainty—and, remember, our prices are low by world standards to begin with—allows us to plan and invest to meet this challenge. The alternative, ad hoc price cuts and poorly conceived pricing policies introduced without consultation, make it very difficult to meet these hurdles. Lilly will meet the current challenges the way it always has: we will find new and better medicines and we will bring them to the world. Lilly is investing enormous sums to make this happen. You will see from our submission that Lilly is investing significantly in Australia. We are proud to be associated with some groundbreaking Australian products and technologies.

The pricing certainty provided by the MOU helps here as well. Along with a range of factors, certainty of pricing for medicines helps make the case for local investment. One example is Lilly's cornerstone investment in the new US$250 million dedicated biotechnology fund headquartered in Brisbane. Through this fund, Lilly and other investors will develop new local discoveries and help build the biotechnology industry that is already rapidly developing in Queensland. Lilly finds new medicines that help people live longer, healthier,

better lives. We are working to find breakthroughs like the one made with insulin in the 1920s—this time with cancers, mental health and, we hope, Alzheimer's disease. The certainty provided by the MOU plays a key role in supporting these efforts. We respectfully request the committee to support the bill.

Ms Waterhouse—Thank you for the opportunity to talk about why this legislation is so important to my company and also to Australian patients. The pharmaceutical sector in Australia and our relationship with government is quite unique amongst Australian industries. The majority of our products—the medicines and vaccines that Australians need to prevent disease, treat disease and stay healthy and productive—are not accessed by consumers in a free market. The majority of our medicines are purchased by the government on behalf of the community, to be prescribed by health professionals as they are needed, and those who need them make a modest contribution to the cost in the form of a co-payment. My company, like others and many of my colleagues here today, have our Australian prices determined by the value of the health outcome they produce as assessed by one of the most rigorous health technology assessment processes in the world: the PBAC. Because of all these factors, we recognise that the PBS is a critically important component of Australia's healthcare system, because it is the way the majority of our products are purchased, and it is also a critical component of our ability to sustain a viable business in Australia.

Therefore, a financially sustainable PBS is not just in the long-term interests of Australian patients and taxpayers; it is in the long-term interests of industry. We take our role seriously, in partnership with government, as co-stewards of the PBS. The current MOU builds on the 2007 PBS reforms. However, it recognises that we have a brand-new financial environment as a result of the global financial crisis. Therefore, we need to preserve the principles of support for innovative patented medicines but we also need competition in the off-patent area. I was part of the core team that worked on negotiations with the government. It was a tough set of negotiations, but at the same time we knew that we had to be part of the solution and not part of the problem.

GSK's heritage in Australia goes back to 1886. We know how important it is to have the right operating environment to thrive. Over the years we have built a strong and diverse business which now produces about $1 billion worth of exports per annum. We have five sites in three states—Victoria, Tasmania and New South Wales—and we provide about 1,600 skilled jobs in our four manufacturing plants. We have deep and long collaborations with Australian researchers and doctors and we invest about $45.2 million per annum in local research and development.

We are a major provider of off-patent medicines, with a number of product coming off patent in the current years. This means that we will be taking hit to our bottom line. Over a quarter of GSK's business is in off-patent medicines. If this legislation goes through, for us that means going from being a growing business over the next two or three years to actually being a business whose revenue does not grow. We, like other MA members, will therefore be directly affected by the proposed price cuts and price disclosure rules. But the crucial factor for us and why we strongly support the legislation is that the certainty of the savings allows us to plan appropriately. We have already factored them into our budgets and business plans for the next two or three years.

Without the legislation that you are considering, the business environment becomes much more uncertain for us to manage. I will give you an example. We are currently putting a proposal to our organisation for significant investment in our Boronia site in the east of Melbourne. The proposed MOU and all that goes with it is a very, very strong reason why, given the certainty it would give us, Australia remains a very good place to invest. There will not be any ad hoc surprises or things that come up that we were not expecting which will knock the company off course. It is really helpful in building a stronger organisation within Australia to have that level of certainty. We believe that the legislation before you is entirely consistent with and builds upon the set of PBS reforms passed by the Australian parliament in 2007, the important aspect of which is realising the savings available from competition in the F2 formulary but at the same time retaining the capacity to fund innovative new medicines in the F1 formulary. That is why we are supporting the legislation today and we would urge you to do the same. Thank you.

Ms Orr—Good morning. I appreciate the opportunity to appear before the committee to reiterate MSD's support for the legislation proposed. I would like to outline the reasons for our support. MSD have been operating in Australia for nearly 60 years and we have had manufacturing facilities here for nearly as long. We employ over 800 people. We are one of Australia's largest exporters of manufactured goods, with exports this year of about $1.5 billion.

We have a proud history of bringing valuable new medicines to Australia and to the world. Our discoveries include the first measles vaccine and the first statin, which is the most widely prescribed medicine in the world for high cholesterol. We are extremely proud of our most recent breakthrough, and that is working with Professor Ian Frazer at the University of Queensland and with CSL to develop and make available Gardasil, which was the first ever vaccine in the world to protect women and young girls against cervical cancer.

MSD has a number of widely used medicines whose patents have expired over the last few years, particularly in the area of heart disease, osteoporosis and glaucoma. Currently, about 25 per cent of our business comes from off-patent medicines, which compete alongside generic medicines. We are one of the MA member companies who will be hardest hit by the price cuts delivered by the bill. As one example, the PBS price for simvastatin, a cholesterol-lowering medicine, is expected to drop significantly due to heavy discounting from generic companies, which already applies. The price drop for this product alone will have a major impact on our revenue. However, business certainty and a stable policy environment are paramount for us and this is why we support the bill so strongly.

We have a number of new innovative products in our pipeline to treat a broad range of diseases. The legislation in this bill will provide the certainty we need so we can continue to invest in our local business and employ the people and skills we need to bring these medicines to Australia.

As financially painful as the price cuts will be for MSD, we recognise that there are pressures on the PBS which have been compounded by the global financial crisis. If cost savings need to be made then the most appropriate and fair way to deliver these savings is for the price paid by the taxpayer and consumer to more accurately reflect that being offered by companies to pharmacists in the marketplace for off-patent or generic medicines.

As highlighted by Will Delaat, Australia pays around 20 per cent less on average than other OECD countries for patented medicines yet comparably high prices for generics. A sustainable PBS is vital to MSD's long-term business in Australia. The changes outlined in this bill will create a more efficient system so that the PBS can continue to provide patient access to a wide range of medicines, new breakthroughs as well as older generics. This will benefit the consumer, the government and all of the Australian medicines industry.

Senator SIEWERT—Can I pursue the percentage issue. Does Medicines Australia provide 86 per cent of all prescriptions?

Mr Delaat—It's the cost of those prescriptions.

Senator SIEWERT—And 60 per cent of the cost of generics?

Mr Delaat—Yes, the cost.

Senator SIEWERT—Is that 60 per cent of the cost what the GMiA was talking about? Do you provide the higher cost end of the generics market?

Mr Delaat—I fail to understand that whole argument, listening from the back. There are no higher cost generic medicines other than about 25 per cent of off-patent genericised medicines that have a small premium. You can apply a small patient premium. The generic company could do it but they do not, of course, but, certainly, the originator companies often do. Today about 25 per cent of those medicines have a small premium of 50c or a dollar.

Senator BOYCE—That would be because that is the known brand and people would know that as the medicine in that area.

Mr Delaat—Yes. There are lots of good reasons why people want to stay on the original brand. Often people on psychiatric medicine get freaked out if they get swapped around from brand to brand and so they want to stick with the one brand they have known for 10 or 15 years.

Senator SIEWERT—Do 25 per cent of all the off-patents have a premium?

Mr Delaat—Twenty five per cent of all the off-patent medicines have a premium. The government only reimburses at the same level whether it is it an originator's off-patent medicine or a generic company's off-patent medicine. It is then a question of the discounting which takes place beneath that. The generic companies will discount, sometimes extremely heavily, in order to get their product on the shelf of the pharmacy, particularly when a product has come off patent. The fact of the matter is that the government only ever reimburses at the same price whether it is a Glaxo or Merck off-patent product or an Alphapharm or Sigma product. I did not understand that whole argument. The only higher priced off-patent medicine is where there

is a small premium and, as we heard from GMiA, there are some brands of off-patent medicines made by the originator companies that have a small premium and they are probably 25 per cent of those.

Dr Shaw—On pages 18 and 19 of our submission, we have tried to cut the data in various ways. We have the whole PBS market, we have got the off-patent market, we have got by value, we have got by volume and we have gone to some lengths to try and differentiate what we can ascertain to be GMiA members versus Medicines Australia members. Try as we might we could not hit the numbers that the GMiA was talking about. They may have other data that we are not privy to. The exercise we have done in our submission is to try and look at it in different ways and look at the data.

CHAIR—They are all the circles?

Dr Shaw—Yes, they are all the circles. Whichever way you cut it, our members account for the majority of the off-patent market. They may have other data, but we have not been able to recreate it from what we have.

Senator SIEWERT—Where do you get your data from?

Dr Shaw—I would have to take that on notice. I suspect it is IMS Databases, which is pretty much the industry standard for data across the industry.

Mr Delaat—Let me add Medicare data as well. There is always this issue of the under copayments, which I will not confuse the discussion with, and there is the other issue that you will hear about from the generics industry in relation to IMS, which is this third-party collector of data at the pharmacy level. The generic companies do not always supply their data to IMS, so there is some component of the IMS data which is missing. We have ways of compensating for some of those figures.

CHAIR—I have a clarification question. Market share seems to be at issue in terms of discussion. At any time in the open discussions around the ongoing debate about the PBS has there been any agreement or acceptance of a common database between the department/government, Medicines Australia, the generic medicines industry and the Pharmacy Guild? There are all these meetings and advisory groups, and those things have been going on forever. Has this issue about how market share is determined, which has become quite clear in this inquiry and in others, been an issue of discussion?

Mr Delaat—It has only become an issue in this latest debate on the bill. Basically it is a bit of a furphy, really. The government has the data. The government knows who it reimburses. The government has Medicare data on all PBS prescriptions other than the under copayment. It knows how many prescriptions are written for various medicines and who the suppliers of those medicines are because they reimburse the PBS. Whichever way you cut the data, basically we have 50 members and they have five; they have about a 15 per cent share of the whole market, we have 85.

Senator BOYCE—Let's just talk about the generics.

Mr Delaat—We can talk about that too.

Senator BOYCE—What percentage of F2 do you have?

Mr Delaat—We have over 50. We have 60 per cent—on the data that we have available, based on IMS, based on Medicare, based on the government's figures.

Dr Shaw—One of the things that is in the memorandum of understanding that is not part of the bill but is in the agreement we have with the government, you will be pleased to know, is that we agreed to do some work on joint data-sharing on the PBS. Certainly in the time I have been discussing with governments about the PBS, we spend the first half of a discussion arguing about whether the PBS is going up or down, who owns what and what is happening. One of the good things is we agreed with the government that we would have a discussion with them about the data about the PBS—what is happening to it, why it is growing at the rate that it is, who has got what shares. I am sure there is scope for that work to involve other stakeholders as well.

CHAIR—Are there any other questions around data?

Senator BOYCE—There seems to be a suggestion in your submission that GMiA and its members are a bit player in this market. Is that what you are trying to tell us?

Mr Delaat—We are not trying to say that. They are trying to say that, aren't they?

Senator BOYCE—That they are a bit player?

Mr Delaat—Sorry, I thought you said 'big'.

CHAIR—Just for clarification, Senator, that is not in the submission, that is your assessment of it?

Senator BOYCE—Yes, exactly. As I said, it seems to be suggested by what is said.

Dr Shaw—We account for about 60 per cent of the off-patent market by value. The total nonmembers would account for 40 per cent but, of those 40 per cent, some would not be members of the GMiA. So there are some generics companies that are not—

Senator BOYCE—But isn't anything between 30 and 40 per cent still a significant part of the market?

Dr Shaw—It is about a third, yes.

Senator BOYCE—Are they a significant player in the market?

Mr Delaat—Again, it comes back to 'lies, damn lies and statistics': how do you want to read the data? I would not suggest they are a bit player. They are a player in the market as a group of companies, but it depends on whether you look at the cost or you look at the number of prescriptions.

Senator TROOD—We are talking about some figure which is somewhere around 30 per cent.

Senator BOYCE—In excess of 30 per cent.

Mr Delaat—Of the volume.

Senator TROOD—Are you telling us that that is not a significant part of the market?

Mr Delaat—No. That is by volume, not by cost to government.

Senator TROOD—But you made the point earlier—sorry, Senator Boyce, you go on.

CHAIR—Senators, can I intrude for a second. I am not sure where Medicines Australia's opinion about who is a bit player is leading. If you want to talk about the data, that is fine.

Senator FIERRAVANTI-WELLS—Senator Moore, you may have negotiated the agreement with the government. That is really what the point of that is.

CHAIR—That is a question for government.

Senator FIERRAVANTI-WELLS—It is a question for the government. This is about legislation where the government has entered into an agreement with one entity and here it is at issue that that entity has a certain market share and covers a certain number of prescriptions per annum to the exclusion of others, so it is a point.

CHAIR—I will take your evidence and it will be on *Hansard*. What I am saying is that I am questioning the question for this organisation about their opinion. If you have an issue about the process as you have explained, that is a question for government.

Dr Shaw—The figures show that it is about 30 or 40 per cent of market, for the off-patent market—the value that is for the generic manufacturers not MA members.

CHAIR—Please continue.

Senator BOYCE—What I am suggesting is that whilst GMiA might dispute those figures even at 30 to 40 per cent they are a significant player in the market. What was Medicines Australia's view about GMiA not being involved in negotiations with the government?

Dr Shaw—That would be a question for the government but our—

Senator BOYCE—No, I asked what your view about them not being involved was.

Dr Shaw—Our understanding is that, just as we were being consulted from the middle of last year about reforms to the PBS, the government was in various discussions with the generic manufacturers association at the same time. We were in discussions with the government for the 12 months up to the budget. My understanding is that the generic manufacturers were discussing with the government through that period as well. For reasons that I am not aware of, except for what the minister has already said in parliament, they were not able to reach an agreement with the generic manufacturers on a policy approach whereas, through our discussions, we were able to identify policy tools to save the PBS money and make it more efficient and effective.

Senator BOYCE—I have one further question which is not in this area but flows on. The $1.9 billion savings that are expected here what percentage of that will be at a cost to Medicines Australia's members?

Dr Shaw—Given that we have about 60 per cent of the value of the F2 market, I would estimate about 60 per cent, almost two-thirds.

Senator BOYCE—So two-thirds of that will—

Dr Shaw—Just to your other point too about the relative process I think certainly the process that we went through in discussing with the government in 2010 was very similar to the process we had in 2006 in discussing the reforms of the previous government. The similarities are eerie in some ways. In both cases, the government of the day approached us to ask how to find savings in the PBS. Then as now, the areas for efficiency were in the off-patent generics market because generic prices are too high. Then as now in 2006 and 2010, we decided we wanted to be part of the solution not part of the problem and we worked collaboratively with the government of the day. Then as now, I have to say the generics association was opposed to the reforms and from my understanding the generics association did not put forward constructive policy options for savings. In a way they are quite similar.

Senator BOYCE—You are talking about a $1.2 billion cost to your members out of this over four years. What is the pay off for your members?

Dr Shaw—Predicability in policy. As part of the MOU the government has agreed not to introduce any other, the phrase is I think, 'price related policy measures' over the remaining 3½ years of the agreement.

Senator BOYCE—Or any more formularies.

Dr Shaw—No changes in pricing policy essentially. The reason for that is that there is a history of ad hoc policy changes to the PBS over the years. In 2004 we had the 12½ per cent policy, in 2005 there were some other—

Senator BOYCE—But in 2007 there was an agreement that was meant to be a 10-year reform wasn't there?

Dr Shaw—There was no agreement around it.

Senator BOYCE—Sorry, I was not using that in a legalistic way.

Dr Shaw—You are right, there were some major reforms introduced in 2007. Subsequent to that in 2008 there was chemotherapy pricing arrangements and in 2009 there were new therapeutic groups introduced. So what the industry essentially has agreed with the government is that in return for the savings there will be essentially a period of predictability in policy for the remaining 3½ years.

Senator BOYCE—I could ask lots more, but I will stop.

Senator FIERRAVANTI-WELLS—Picking up Senator Siewert's point I went back to some evidence that was given in May this year as part of the other inquiry. Mr James from Janssen-Cilag told us that there were 180 million scripts per annum. Is that correct?

Mr Delaat—Yes, that is right.

Senator FIERRAVANTI-WELLS—Of those, at the time, because we were talking about therapeutic groups, he also indicated that about 75 to 80 per cent of those scripts were concessional. That is about 145,000. That evidence is still fairly current. Can you tell me, of that volume of scripts, to try to put some figures on to this, how many of those scripts are under F1 and how many are under F2? Are they statistics that you have?

Dr Shaw—We would have them. I do not have them in front of me. We probably have those statistics. We could take those on notice—unless you have them now.

Mr Delaat—We have a facts book which we have just released. It has all of this similar information in there. I can tell you that, as of October this year, in F1 there were 478 medicines and in F2—if you combine the F2A and F2T—there were 220 medicines. There were more than twice as many medicines in F1 as there were in F2, and then it is a question of how many of those are concessional versus—

Ms Orr—But also the volumes of each of those medicines.

Mr Delaat—Yes.

Senator FIERRAVANTI-WELLS—My question is: how many scripts are in that? We know there are 180 million scripts per annum. How many are in F1 and how many are in F2? My question also goes to: how many of those in F2 are scripts from companies that are the originators that operate through their generic brands? Do you see what I am getting at? Obviously you have your main pharmaceutical companies that mostly operate in F1. I am trying to put this in simple language.

Senator BOYCE—Good luck, Senator!

Senator FIERRAVANTI-WELLS—Well, I am trying to, because there may be people out there who are trying to understand this in simple language.

Senator BOYCE—Hopefully. I hope someone is!

Senator FIERRAVANTI-WELLS—And these companies obviously operate through their generic brands; am I correct?

Mr Delaat—Well, I am not sure what you mean by 'operate through generic brands'. They have the product still on the market.

Senator FIERRAVANTI-WELLS—They have products still on the market and they—

Senator BOYCE—That is the off-patents.

Senator FIERRAVANTI-WELLS—And then once they come off patent you market them through—or you have companies that also market a similar medicine?

Mr Delaat—Maybe it is best to get my colleagues, because they actually run companies that do this.

Ms Orr—If I use the example of Zocor, which is Simvastatin, which was on patent and—

Senator FIERRAVANTI-WELLS—Could you put it in plain English for people listening out there? I know this is part of our problem.

Ms Orr—You have a cholesterol-lowering medicine called Zocor, which runs out of patent in 2006, 2004 or 2005—whenever. Then generics come to the market and discount at the pharmacy level. Zocor remains on the market, and we still have the right to compete with Zocor.

Senator FIERRAVANTI-WELLS—You make Zocor?

Ms Orr—We make Zocor. It is still called Zocor.

Senator FIERRAVANTI-WELLS—And then you make a generic product that is similar and market it as a generic product through your company?

Ms Orr—We may or may not.

Senator FIERRAVANTI-WELLS—I know that, but the point is that ultimately you have the advantage both when you have it on patent and then when you go into the generic market. Do you see what I am getting at?

Ms Orr—I do not see that it is an advantage in the generic market.

Senator FIERRAVANTI-WELLS—There is a point here about this pricing policy and its potentially restrictive nature—it is in effect a protectionist approach. Are we seeing a protectionist approach as the trade-off to pharmaceutical companies in this country at the expense of the traditional generic market? That is my question. That is the legitimate gripe. I am putting to you the legitimate issue that the generics industry have put to us. It seems to me, given the way this agreement came into being, that that is a legitimate gripe of the generics industry in Australia. Can I just have your comments in relation to it?

Dr Shaw—Sure. I think our view has always been that we want the off-patent market to be a level playing field in terms of competition. So, yes, a number of our members have a lot of business in the off-patent market, and I think our approach has always been that some of our members want to compete in that space. They want to compete alongside generics. They want to open up the competition in the market to compete alongside them and drive the price down. So we are not seeking any special favours, and I disagree that the MOU or any of the legislation has any special favours for our members. Our view has always been that we want a level playing field so that our members can compete alongside the generics companies.

Senator FIERRAVANTI-WELLS—But when you talk about a 'level playing field' your level playing field is a generic player that has the backing of a major pharmaceutical company as opposed to a generic player. That is a legitimate question for the public out there, who potentially see a generic player in Australia manufacturing drugs in Australia and the big pharmaceutical companies. We talked about perception in the past. That is really what the perception is out there. It is not a level playing field for the generics in Australia. It might be viewed as a level playing field from your perspective, but you have the benefit of major international pharmaceutical companies backing up the generics that will be playing in this field.

Ms Orr—Some of the GMiA members also have the backing of major international pharmaceutical companies.

Senator FIERRAVANTI-WELLS—I am asking the question because it has been put out there as criticism and I am giving you the opportunity to deal with it.

Dr Shaw—The reality is that all the GMiA members are foreign owned major international pharmaceutical companies.

Mr Delaat—Other than Sigma.

Dr Shaw—Which is shortly to be purchased by a South African company. So, apart from Sigma, which is currently moving to foreign ownership, all of the companies are foreign owned.

Senator BOYCE—So they have become like the majority of your members.

Dr Shaw—They are international pharmaceutical companies. Some of our members are Australian owned companies. Some of our members are international companies. Some of our members have manufacturing facilities in Australia. Merck, Sharp and Dohme have a facility in Granville in Western Sydney. GSK have a facility in Boronia.

Senator BOYCE—I am not disputing that.

Dr Shaw—The point is that there are more similarities than differences in the membership of the GMiA and Medicines Australia. They are international companies that have manufacturing facilities in Australia; Medicines Australia members are international and Australian pharmaceutical companies of which a number have manufacturing facilities in Australia.

Senator TROOD—They are significant players in the market, aren't they?

Dr Shaw—They account for 30 to 40 per cent of the off-patent market.

Senator FIERRAVANTI-WELLS—And now I come to the next point: when were you approached by the government? We have heard evidence that there were discussions that the government was having with all players in relation to general reform of the PBS. When did your discussions with the government become about not just reform of the PBS but also an agreement? Did the government propose an agreement to you or did you propose the agreement to the government?

Dr Shaw—I think it was more organic than that. We had certainly been discussing with the government since probably the middle of last year. We talked a lot about the PBS and growth trends and, in fact, put some of the proposals the generics had previously put to the government as well. Further discussions went through. I think we were talking about this before. February or March of this year was when we started conceptualising there was enough agreement on the policy tools that could be used, that we started talking about finding some sort of agreement on this. We had our issues and the government had their issues. So it was probably around February or March that we started talking about it. I am not sure 'memorandum of understanding' is the right phrase—it was too embryonic at that stage—but we talked about some sort of understanding or agreement about the PBS.

Senator FIERRAVANTI-WELLS—As part of those discussions was it a condition that you would be the sole negotiator o any potential agreement?

Dr Shaw—No.

Senator FIERRAVANTI-WELLS—So you were open to the government having as part of that negotiation process entities other than yourself?

Dr Shaw—Yes. The way the government conducted the discussions this year was very similar to the way they happened in 2006. In 2006 the government spoke with each of the stakeholders. The same occurred to the pharmacy people as well. We were not part of the pharmacy people negotiations.

Senator FIERRAVANTI-WELLS—But that did not result in an MOU.

Dr Shaw—They have reached a five-year agreement with the PBS.

Senator FIERRAVANTI-WELLS—But that is separate. They have a five-year agreement. This is separate to that. You have an MOU, as I understand, in the same space as a five-year agreement. We know the five-year agreements have been negotiated according to a specific process. This time the difference is that there is an MOU that has been negotiated with one entity. Is that not a fair assessment of the situation?

Dr Shaw—Yes, we are in significant agreement.

Senator FIERRAVANTI-WELLS—Okay, so you have one entity that has negotiated with the government—exclusively one entity, as opposed to other entities. My question to you is: was the decision

about one entity sole negotiator and party to this agreement a decision of the government, or was it a condition that you put on the outcome?

Dr Shaw—I do not believe it was a condition we put on the discussions.

Mr Delaat—No. I can vouch for that. I was at all of the negotiations, as was Deborah Waterhouse. That was never, ever discussed; it was never, ever a condition.

Senator FIERRAVANTI-WELLS—At any stage did you not think it would be reasonable to, or did you suggest at any time that it would be appropriate for the government, given the market share that other entities have in this space, to have discussions with them as well?

Dr Shaw—Quite possibly, but I guess the discussions we were having were budget in confidence, so at no stage—

Senator FIERRAVANTI-WELLS—Dr Shaw, you either did or you didn't. My question is did you make that suggestion to government? That was either a yes or a no.

Dr Shaw—To be honest, Senator, I really do not recall. The reason we were not able to consult with the generics or the pharmacy or any other stakeholders either inside the sector or outside is because they were budget-in-confidence measures and it would have been imprudent of us to talk externally with other stakeholders when we were having those discussions.

Senator FIERRAVANTI-WELLS—When was the agreement struck to enter into an MOU? When did you agree with the government that you would sign an MOU?

Dr Shaw—March or April. It was probably around April. I think that is right.

Senator FIERRAVANTI-WELLS—Okay, so at that point, March-April, and it was the government that said, 'We will enter into an MOU with you'? Or did you say, 'We want to enter into an MOU'? Do you see what I am getting at, Dr Shaw?

Dr Shaw—Yes.

Senator FIERRAVANTI-WELLS—There is a lot of criticism. There is a legitimate gripe by a sector of your industry that says it has not been consulted, and I want to understand who is responsible for the lack of consultation. Is it Medicines Australia perceiving a potential protective and market share advantage for its members, or is it the government failing to properly consult across the board—irrespective of what it could afford and irrespective of the fact that it would likely result in a protectionist view of what the agreement would give? Do you see what I am getting at?

Mr Delaat—Absolutely. I want to take you back to an earlier comment from Dr Shaw that in the 2006 discussions that led to the 2007 reforms the same dynamic occurred—that is, there was some splintering across the industry of discussions with the government. It was no different then to this time around. When the government engaged the different sectors of the industry to come up with constructive proposals, we felt that we were being very constructive in our proposal. We had no idea what was being discussed with other parts of the medicines industry but, similar to 2006, I can only imagine that there was also a breakdown in the constructive nature of those discussions. It was not for us to suggest to the government how they went about entering into those discussions with the other sectors.

CHAIR—Senator, I am going to pull you up there. I am looking at GMiA. You are fully able to provide supplementary information to our committee, but I do not have the capacity to answer hands in the air. That applies to all witnesses. If you hear any evidence that you wish to respond to, could you please provide it to the secretary.

Dr Shaw—I have the transcript from the Minister for Health and Ageing when he was announcing the PBS reforms in 2006. There are a couple of sentences here that are worthy of repeating. This is the Minister for Health and Ageing in 2006, Tony Abbott:

The other matter that I should briefly touch on, the Generics Medicine Industry Association is not, as I understand it, especially happy with these changes. It believes that these changes will make it harder for them to maintain market share by removing the scope for them to offer discounts to pharmacists.

I make a couple of points in response. First of all, I point out that 70 per cent of the Australian generics market is occupied by companies which are not members of the Generic Medicines Industry Association, they are in fact members of Medicines Australia. They are the manufacturers and marketers of innovative patented drugs as well as of off-patented drugs.

The other point I make is that we are, as part of these changes, ruling out a tendering system and I think that the whole sector, including GMIA, should be pleased that we are not going down the New Zealand path.

The final point I would make is that by removing the gross discounts from the system, we should ensure that domestic generic manufacturers are less at risk from predatory newcomers such as some of the Indian generic drug manufacturers.

I am happy to table that if that is helpful.

CHAIR—That would be useful, Dr Shaw, and with full understanding that that does belong to 2006 and that circumstances may have changed.

Dr Shaw—It illustrates that the issues we are dealing with today are not that dissimilar to 2006.

CHAIR—Which is the point you made in your opening statement.

Senator FIERRAVANTI-WELLS—I know that but my point is specifically this: now we have an MOU there is a difference to the circumstances in 2006. They were broad reforms which resulted in a consultation process across the industry. In fairness, I appreciate, Dr Shaw, what you are trying to do—and that is to implicate Mr Abbott in terms of what happened.

CHAIR—Senator, that is not an appropriate statement. If you are wishing to make that accusation, Dr Shaw must have a chance to respond.

Senator FIERRAVANTI-WELLS—That is in a positive way. I am just simply saying that Dr Shaw is trying to draw the analogy—

CHAIR—The comparison—

Senator FIERRAVANTI-WELLS—The comparison. The reality is that the difference here is that you have a memorandum of understanding which is separate to another process. That is really the issue here. So I think it is inappropriate to compare apples with oranges, because we are really talking about an agreement that was entered into with one entity whereas in 2006 we are talking about reforms that applied to the whole industry that were brought into being following consultation with everybody in the industry. That is the point that I really want to stress.

CHAIR—And you have made it.

Senator CAROL BROWN—With the F2, Medicine Australia's members will be competing with the same rules and laws as the generic drug companies—GMiA members.

Dr Shaw—Correct. There is no special treatment.

Senator CAROL BROWN—So it is the same across the board?

Dr Shaw—Yes. In fact, the current incentives to promote generics will still exist. I would have to check the figures but I think there is a $20 million generic awareness campaign the government is introducing to promote the use of generic medicines. The other existing incentive I think is now $1.53 for pharmacists to dispense a premium-free medicine, which historically has generally benefited generic manufacturers. That will continue as well. We have agreed that those incentives can continue. As far as I am aware, there is nothing in the MOU that specifically advantages our members over nonmembers.

Senator CAROL BROWN—It seems the government is looking for a big plus on the F2 pricing for the taxpayer and Medicines Australia is looking on F1 for a big plus in health outcomes for Australians. Is that it, putting it simply?

Dr Shaw—The prices for F1 by international standards are low already. There are various control mechanisms. We have the PBAC that does cost-effectiveness evaluation. We have reference pricing operating on F1. In F2, we know that the prices Australia pays for off-patent generic medicines are high by international standards. We know that there are many medicines where there is quite widespread discounting going on.

Senator CAROL BROWN—Just on that point, do you have any percentage figures that you can give us?

Dr Shaw—I have some media stories from a few years ago about how some drugs have been discounted. Simvastatin has been discounted between 50 to 70 per cent. While the taxpayer is paying $100 for a medicine, the manufacturers are in fact selling it at $30. Similarly, with Fluoxetine or Prozac, some of the news stories are talking about discounts of 50 per cent. We also have some news stories quoting generic manufacturers talking about the fact that generally speaking their starting discount is 50 per cent and then to get into the market they have to go up to 70 per cent. The issues with those two drugs I have mentioned in particular is that they have not been subject to price disclosure. So the 2007 reforms brought in transparency, but those two

drugs have not been caught up by price disclosure. The changes that are in this bill that you are reviewing will make sure that those drugs get captured in that calculation.

Senator CAROL BROWN—I have been reading about loyalty programs that are offered as well so that pharmacists will stock certain brands. This piece of legislation is for the government to actually pay a weighted market price.

Dr Shaw—That is right.

Senator CAROL BROWN—So you would not describe it as a cynical cash grab from the government?

Dr Shaw—The only cash grab that is happening here is that the taxpayer is paying $100 when the manufacturer is selling it into the market at $30.

Senator BOYCE—How much?

Dr Shaw—I am just using a hypothetical example. The taxpayer is paying for a medicine at $100, whereas the manufacturer is selling it into the market at $30, so there is a lot of discounting going on at 50 per cent, 60 per cent and 70 per cent.

CHAIR—But there is no evidence of that. That is from media stories.

Dr Shaw—I have some media stories I can table.

CHAIR—You are making that statement based on media stories?

Dr Shaw—Yes.

Senator BOYCE—It is like your members—you have the lion's share of the market, as you pointed out.

Dr Shaw—I have been working in the industry for seven years, and I get anecdotal evidence from managing directors. I can tell you the two things that managing directors have told me over the years. One is that they cannot believe the low prices that are offered for new medicines in Australia. The people who come from overseas, particularly, cannot believe the price that is put on the table for a new medicine when they are trying to get it through the PBAC process. It is one of the reasons that it takes three years for a new medicine to get on the PBS. The other thing I have heard from more than one managing director over the years is the remark about how much discounting goes on at market. They cannot believe how much it happens here compared with other countries. I have had more than one managing director quietly say to me over the years, 'I can't believe our company is still making money on this product when, in other markets, we have abandoned it because the price is so high here.' They comment that they are still making good money in the off-patent market, whereas in other markets like the US and the UK their company has got out of it because the prices are too low.

Mr Vermeer—As a company that has a very small off-patent portfolio right now—only a couple of per cent but in a couple of years time it will be 66 per cent of our portfolio—we do not—

Senator Boyce interjecting—

CHAIR—Could you let the witness end his question rather than our having to hear your commentary.

Mr Vermeer—We do not view the legislation as protectionist. Inside our company we view it as pro-competitive, because it is bringing to light discounting that is happening, unseen by the government and the taxpayer, into the light, and that is a fundamentally pro-competitive activity. That is going to hurt our company, and we have to make a decision on what level of discounting we do. But, in reality, these discounts are happening now. They are just being brought forward and being made apparent by the legislation.

Senator CAROL BROWN—Continuing on from your comment, we have heard some evidence here today about patent cliffs—there will be a lot of drugs that will come off patent—so the generic market will increase.

Mr Vermeer—Absolutely.

Dr Shaw—There are $2.3 billion worth of medicines going off patent in the next few years. That is going to open up enormous opportunities for the generics market. They are already seeing an increased market share—and I have some figures here that we can table, if you like; they show the market share and that generics are increasing. The reforms augment the reforms that the Howard government introduced in 2007 to drive more competition in the generics market and make a more competitive generics sector. At the end of the day, the price cuts are going to occur only where companies are already discounting anyway. So, really, the companies are the masters of their own destiny in this. If they are not discounting, there will be no price cuts. It is the market that decides the outcome. That is not so dissimilar from the reforms introduced in 2007. What we are

doing is making sure that it is mandatory so that companies cannot opt out of the disclosure process, which may have been happening, and we are making sure that all products and F2 are being subject to the same market transparency provisions that a handful of drugs have been to date. That is what the bill is all about. Essentially the bill is about whether taxpayers should forgo $1.9 billion in savings so that a handful of generics companies can continue to have taxpayers subsidise their rebates. That is essentially what the bill is about.

CHAIR—Thank you very much. There probably will be questions on notice.

Senator TROOD—I have two areas that I would like to explore.

CHAIR—You will have to put them on notice, Senator.

Senator SIEWERT—This is a question on notice. Are you able to provide the data on which the pie charts mentioned in your submission are based?

Dr Shaw—Yes.

CHAIR—Senator Trood, there are two areas you may wish to follow up and then we will be able to give those questions on notice to the group.

Senator TROOD—I would like to clarify the issue of market share, which I still think is not clarified. I also want to explore the question of incentives to improve the take-up of generics and lower the prices of generics, which seem to me to be issues that have not been properly explored.

CHAIR—We already have questions on notice to both this group and GMIA and we will be asking the department as well about the market share question that has already been identified. The areas around incentives for generics—where do you want to go with that?

Senator TROOD—May I ask this question?

CHAIR—Yes.

Senator TROOD—It seems to be common ground, and I think you agree, that the generics market is growing—I think you said that, Dr Shaw—but that, compared to other countries, it is still a modest proportion of the overall pharmaceutical market. Is that right?

Mr Delaat—No.

Senator TROOD—And you say, as I understand it, that you support incentives to take up generics and you have alluded to the package that was in place. Is that right?

Dr Shaw—I think we said we agreed to the continuation of the existing incentives, yes.

Senator TROOD—So you are happy to have incentives to try and encourage generics, is that right?

Dr Shaw—The ones that are there at the moment, yes.

Senator TROOD—That is what I am saying—you support the existing incentives.

Dr Shaw—Yes.

Senator TROOD—Earlier, you heard GMIA talk about incentives. From the perspective of the government or the consumer, why would it not be in the interests of the PBS to place greater incentives in the market—to provide more incentives for individuals to take generic drugs?

Dr Shaw—Because they are not necessary, I think.

Mr Delaat—We should clarify the first point, because I think we are coming off a wrong base. You talked about the market for generics being small but growing. In fact, the figures I have in front of me show that something like 60 per cent of the market in prescriptions—and 35 per cent of it in value—is in the off-patent market. So there is no issue with how many prescriptions there are in the off-patent market. The only issue is what the percentage supplied by the generic companies is and what the percentage supplied by our member companies is.

Senator TROOD—At this stage, I am not troubled by who is supplying what. The point I am interested in is increasing the incentives for the use of generics, which everybody recognises are lower cost medicines with equal pharmaceutical value—they have the same kinds of consequences for the individuals who take them.

CHAIR—Mr Delaat, we have asked a similar question to GMIA on notice. Can we get the Medicines Australia response on the issue, which we have had clarified by Senator Trood, of incentives for generic medicines—your position on that? We would like that taken on notice and responded to by the end of the week.

Dr Shaw—The quick answer is that it will not save the government any money, because the government pays the same price for a generic brand of a medicine as it does for an originator brand of a medicine.

CHAIR—There seems to be some disagreement from some of the people in the room. Once again, I say to people: if you have comments on that, could you get them to us? We need the information by the end of the week. It is a core issue. Senator Trood has been following it up with a series of questions.

Senator TROOD—It may or may not save the government money. I am not sure I agree with you on that proposition, but in fact it would save the consumer money, would it not?

Mr Delaat—No, not at all.

CHAIR—No, it is a set price, Senator.

Mr Delaat—It is a set price.

Dr Shaw—This is the issue about level playing fields. One of the concerns you would have is to avoid carving out market share for one group of manufacturers without saving the government any money. If, as you said, the government is paying the same price for a medicine regardless of whether it is an originator company that makes it or a generics company, and if you have an incentive that carves out market share for one group of drug manufacturers over another group of drug manufacturers, that is less to do with health outcomes and more to do with carving out market share for particular manufacturers.

Senator TROOD—As distinct from preserving your interests in the market.

Dr Shaw—As I said, our interest in the market is that we want a level playing field. Our members want to be able to compete on the same basis as other companies.

CHAIR—Senator, I think we are going down the track of getting information through questions on notice. Mr Delaat, you know the Senator's interest, as do GMIA. We would like your responses to those issues to us by the end of the week.

Proceedings suspended from 10.55 am to 11.05 am

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

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

CHAIR—I welcome representatives of the Consumers Health Forum. You have all the information on parliamentary privilege. The committee has before it your submission—thank you. I invite you to make an opening statement and then we will go to questions.

Ms Bennett—We appreciate the opportunity to be here today to talk to you about this very important issue for Australia's health consumers. Consumers have told us that they want timely access to affordable medicines and that it is essential to them that the PBS remains viable into the future to achieve that. We therefore support the reforms that contribute to the continuing sustainability of the PBS while ensuring that consumers can get the medicines they need at a price that they and the government can afford. The bill gives legislative effect to the MOU between the government and Medicines Australia. We consider that the MOU will contribute to that long-term sustainability and the viability of the PBS through statutory price cuts and strengthened price disclosure mechanisms for the formulary 2 medicines.

Price disclosure basically means that the government is not paying more than the market price for these medicines. It has already demonstrated significant savings in the 160 brands it currently applies to and we believe the additional savings will be substantial. Industry has guaranteed that the price disclosure round concluding in April 2012 will deliver a minimum weighted average price reduction of 23 per cent. Consumers as both buyers of these medicines and taxpayers will pay less for medicines than under the current arrangements, due to the price cuts and the resulting potentially greater competition and further reduction in prices for generic medicines, particularly in the under co-payment market.

We also welcome the provisions in this bill that will enable faster access to safe, high-quality medications through the mechanisms in the bill that allow for parallel registration and reimbursement processes by the TGA and the Pharmaceutical Benefits Advisory Committee, the managed entry of new products onto the market and the 'best endeavours' commitment to a maximum time frame of six months for cabinet approvals of medicines.

We acknowledge the importance of a viable industry to future sustainability, and the policy and pricing certainty of this bill provides for that. We have reviewed the submissions of the Generic Medicines Industry Association and note GMIA's arguments that the strengthened price disclosure arrangements will threaten the ongoing viability of the generic medicines industry in Australia. We have also reviewed the positions of other stakeholders, including the Department of Health and Ageing and Medicines Australia, and their arguments that the viability of the generic medicines sector should not be threatened by this legislation. This is particularly in light of the continuing expansion of the generic medicines market and the prospect of the $2.3 billion worth of medicines coming off patent in the next 12 years.

We note that Australians are paying a premium for generic medicines over and above the prices paid in comparable countries and that this bill will not impose a price on the generic market but rather ensure that the government pays only the average weighted price already charged by the suppliers. This may lead to some change in the generics market given that it has enjoyed high prices in this country for many years, and ultimately it is consumers who are paying for that. The value of a robust generics market in Australia is its capacity to provide cheaper medicines to consumers. If that is not happening, then we question how much benefit or incentive the generics industry provides to Australian consumers. Clearly, however, we would expect the government will closely monitor the impact of the legislation and act on any unintended consequences in market supply that will affect consumers.

We have noted the arguments in several submissions that consumers may face disruptions in medicine supply due to the minimisation of stock by pharmaceutical wholesalers and pharmacists prior to the price reductions. Pharmacists and pharmaceutical wholesalers both have clearly defined obligations to ensure timely access to PBS medicines for consumers and, importantly, we would expect them to meet their obligations to consumers. We argue that it is essential that consumers are not affected by price change arrangements and can continue to access their medicines as normal. At the very least, we would ask that the impact of price reductions on consumer access to medicines is closely monitored.

The other issue that is raised repeatedly in the submissions is that of consultation. We recognise that the MOU grew from discussions with Medicines Australia and that the government did not necessarily intend to negotiate an MOU when these negotiations commenced. In this case, the outcome of these negotiations will be

beneficial, we believe, to consumers. However, it is clear from other submissions that we are not the only group to consider that the negotiation of the MOU would have been strengthened by consultation with other affected parties. CHF argues that the process for the negotiation of future agreements of this kind should involve consumer consultation. We are the people who pay for and use medicines in Australia.

In conclusion, it appears that the MOU and this bill will deliver benefits to consumers through the improved access arrangements, price reductions and cost savings that will ensure the ongoing sustainability of the PBS. We believe that the impact on the generics industry should be monitored and any disruption to supply of essential medicines must be minimised. CHF has consulted widely with our members on this bill and has formed the view as a result of that membership consultation that the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010 should be supported.

CHAIR—Ms Wise, do you wish to add anything at this stage?

Ms Wise—No, I have nothing to add.

Senator BOYCE—I would like to ask you to respond to a couple of the claims of the GMIA, who are obviously opposed to this. They have made the point that in their view some manufacturing of generic medicines may go offshore as a result of this agreement. What is your view on that? What would be your concerns if that is accurate?

Ms Bennett—Thank you for the question, Senator. We do not know what the potential impact of this bill might be in real terms, and I guess nobody really does, but there is no clear evidence that that would be the case. The $2.3 billion of medicines that are coming off patent in the coming few years gives us some surety that there will be a high-value, high-yield market available to those generic suppliers who are able to compete in the market and provide reasonable prices for consumers. Those concerns are less important to us than what consumers are currently paying, which we know are prices that are quite high compared to other comparable countries. We would want to see that this is an industry that can compete in order to ensure that consumers pay much lower prices than they are currently paying.

Senator BOYCE—As you have said, the outcomes of this move are disputed, at the very least. Are you comfortable with what is in effect a four-year price freeze and freeze on new formularies?

Ms Bennett—For us the benefit of this bill is that it does deliver very significant cost savings to consumers both in terms of their capacity, through the price cuts, to buy medicines and also in terms of being taxpayers. It ensures that the government, and therefore taxpayers, are not paying more for these medicines, because they are paying more of the true cost of what companies are currently supplying these medicines for. To us that is a huge benefit to consumers that warrants some level of certainty for the industry. We do value a viable industry in this country; that is important. This bill will provide some policy and pricing certainty, which will guarantee the future sustainability of the PBS, which is also fundamental to consumers.

Senator BOYCE—Does the forum place a premium on the Australian manufacture of medicines, or is where they come from not relevant to your organisation?

Ms Bennett—What we are concerned about is the quality and safety of medicines, and we know that that is guaranteed. The quality and safety of generic medicines is not in question—

Senator BOYCE—I am not asking about quality and safety; I am asking about the place of origin.

Ms Bennett—The place of origin does not enter into the equation for us. What is of concern to consumers is that they get quality, cost-effective medicines. The place of origin is not a key issue for consumers.

Senator BOYCE—You must have had complaints over the years about supply chain issues with overseas manufactured medicines.

Ms Bennett—There have occasionally been issues raised with us, particularly about niche market drugs, where there is only one brand of the product available on the market and suddenly the manufacturer withdraws that particular medicine.

Senator BOYCE—I am thinking not so much of withdrawal but of the difficulties that arise when you need a three month lead time rather than a three or four week lead time.

Ms Bennett—Clearly, from a consumer perspective that would be a real concern, and we would be taking that up with government at the point those sorts of disruptions occurred.

Senator BOYCE—The suggestion has been made that the manufacturer of a patented drug, when it goes off patent, can get a small premium—I think that was the term used by Medicines Australia—for that drug,

even when it is off patent, because it is the recognised brand name in that field. There have been suggestions made about ways you might encourage consumers to purchase generic brands rather than the known brand name. What is the forum's view on this?

Ms Bennett—The kinds of incentives we have heard being talked about include cost signals to consumers. We talk to consumers all the time and they tell us they have great difficulty in being able to put food on the table, pay their electricity bill and then buy medicines as well. For many people there is a choice, and cost is a clear barrier. We know that out-of-pocket costs are increasing right across the health spectrum, not just in terms of medicines.

Senator BOYCE—But we are suggesting that there would not be a cost if you chose the generic medicine, not the previously patented medicine.

Ms Bennett—If the generics market were working really well and producing a really high-value, low-cost alternative to Australian consumers then we would be absolutely behind that. Our concern is that that does not appear to be happening. The international data supports the fact that this is a relatively high-cost industry compared to other countries.

Senator BOYCE—Do you mean high priced?

Ms Bennett—High priced. It is an industry that provides relatively high prices compared to what consumers in other countries are being asked to pay.

Senator TROOD—Do you mean specifically in relation to generics?

Ms Bennett—Yes. If there were arrangements that enabled greater cost benefits to consumers in the generics market we would absolutely support that. We believe that price disclosure enables a truer price to be paid for medicines that reflects the market price and could potentially encourage greater competition. That could then be passed on to consumers, whereas currently that is not happening.

Senator CAROL BROWN—Are there obligations on pharmacists and wholesalers to maintain supplies of PBS drugs?

Ms Bennett—Yes. Our understanding is that the wholesalers, through the community service obligations, must supply drugs within 24 hours—I think there is a time frame on that—and pharmacists, through the Fifth Community Pharmacy Agreement, are also obliged to ensure that supplies are stocked so that consumers do not experience disruptions to supply.

Ms Wise—I will just provide a bit more detail there. The community service obligation funding pool requires wholesalers to supply the full range of PBS medicines within 24 hours to all pharmacies in Australia, while the Fifth Community Pharmacy Agreement requires pharmacists to keep adequate medicine stocks for the supply of pharmaceutical benefits to ensure reasonable and timely access to those medicines by consumers.

Senator CAROL BROWN—Given those obligations, you would not see that this legislation would disrupt supply of life-saving generic medicines?

Ms Bennett—It certainly should not. Given that, at the pharmacy end, pharmacists have now struck a $15 billion agreement with the government, which is a very substantial agreement for Australian taxpayers—and consumers, ultimately—we would expect that they would fully meet the obligations that they have been rewarded for under that agreement.

Senator CAROL BROWN—Do you have any evidence that you would like to give us about the savings that have come out of the 2007 reforms?

Ms Bennett—We understand that the savings have been quite substantial—I just do not have the figures at hand—and in fact are projected to be almost double what the government originally anticipated. That is a good result. It is a good result for taxpayers and, ultimately, if that money goes back to benefit consumers through better health services, then that is a good result too. I do not buy the argument that, because we are making savings on the PBS that are more than we anticipated, we therefore do not need to continue to be vigilant about the sustainability of the PBS. It is an ongoing challenge to ensure that we reduce the costs of the PBS, because our whole health system needs the attention and the funding that will enable it to be sustainable into the future.

Senator CAROL BROWN—And you do not see this legislation as being a threat to the viability of the generic industry? My personal experience when I go to buy medicines is that I am always offered the generic product over the brand-name product.

Ms Bennett—That is a really good question. I do not know for certain that this MOU will not lead to some market exit. Nobody does, probably. I guess it is that safety net of the $2.3 billion coming off patent and the possibility of greater competition that price disclosure provides that could ultimately benefit consumers if it leads to further cost reductions at the supply level. I suppose the market will determine that ultimately, and this provides the opportunity for the market to be more transparent and to deliver potential further savings to consumers.

Senator CAROL BROWN—I do not know if you have read the department's evidence to this inquiry. They indicate on page 17 that GMiA's key ongoing proposal over the period was that patients should be made to pay some $5 more for off-patent medicines made by originator companies than for the same drugs made by generic companies. Do you have a view on a proposal like that?

Ms Bennett—I disagree with that. Consumers are struggling to fund the costs of their health care now. Additional cost signals are not going to be helpful to consumers. Fundamentally the viability of a particular segment of the pharmaceutical industry is less important than consumers' access to essential health and medical services, as far as we are concerned. What matters here is that consumers get the most cost-effective, timely access to necessary medicines.

Senator BOYCE—But aren't the two connected?

Ms Bennett—I think there is an issue about the viability of the industry, but at the end of the day the industry's viability will be reflected through this price disclosure mechanism, which will make the prices that the industry is now charging for these pharmaceuticals to pharmacists more transparent, and ultimately the market will settle around that. But what we are interested in is that consumers get access to the most cost-effective medications.

Senator TROOD—You are interested in and the forum is interested in quality and safety and price, I assume, as being the key indicators of an effective PBS. You have alluded to the incentives in your submission. Do I take it therefore that you would support other incentives that might actually deliver safe, quality medicines at a lower price?

Ms Bennett—What incentives are we talking about?

Senator TROOD—Any incentive that preserves those key elements of the PBS.

Ms Bennett—I suppose there are many different ways that you can arrive at the position that consumers actually pay less and still receive access to high-quality, safe medications. We are looking at this in terms of this particular bill and this is one way that you could arrive at that. We are less concerned about the process and the mechanics of the bill and who was negotiated with and so on versus the ultimate result for consumers. We believe that this is a good result for consumers. Consumers who we have consulted with, our members, believe that. For us that is the critical—

Senator TROOD—I do not think I am disagreeing with you. In fact, I may be in furious agreement with you because it may be that they are desirable objectives for the PBS. My view is, why couldn't we continue to get high-quality safe medicines at a better price and more of them by undertaking somewhat more comprehensive reforms? I suppose my question is, this goes some way down that track but why wouldn't we do more to achieve the objectives that you advocate as a forum?

Ms Bennett—We would be very open to further mechanisms that would achieve that objective—

Senator TROOD—In relation to the therapeutic groups issue, which are now precluded under the MoU and without going into how that occurred, and perhaps you could clarify it for me, that as I understand it is a mechanism by which prices are lowered. So what is your view about the prevention of any further therapeutic groups being created?

Ms Bennett—We strongly supported the development of therapeutic groups because we believe that is one effective way that you can reduce the cost of medicines while there is no concern about the bio-equivalence of the drugs within those categories. The freeze on therapeutic groups in this MoU, I suppose that is the trade-off you get when you need to make the kinds of sweeping cuts, enable price disclosure and enable the access mechanisms that this bill provides. So on balance I think we might not be getting therapeutic groups and that is one mechanism, but what we have got is a really significant range of access and cost measures that deliver real benefits to consumers.

Senator TROOD—My point is, and I would have thought it was yours as well, that therapeutic groups as one mechanism delivers quality and safety at a good price. So why wouldn't you be in favour of those being

continued? What is the trade-off, what is the particular advantage that somebody is getting as a result of therapeutic groups not being presented? Why would you not embrace the idea that this is an undesirable reform?

Ms Bennett—Because therapeutic groups are one mechanism to achieve the sort of cost savings and the sustainability of the PBS that we obviously need to try and achieve. This bill, though, provides very far-reaching significant benefits to consumers and there is no reason why at the end of this particular period of freeze that therapeutic groups could not be reconsidered. I suppose the industry in agreeing to the extent of these price cuts wanted some guarantees and some certainty on pricing.

Senator TROOD—We are looking years down the track through which therapeutic groups are precluded. We are talking about millions, perhaps billions, of dollars which are not going to be saved to the consumer as a result of these being precluded. I am struggling to understand why the forum would think this is a useful reform.

Ms Bennett—We support therapeutic groups and we would certainly support them into the future. I suppose, on balance, when you look at the potential that therapeutic groups provide in terms of savings to consumers versus what this MOU provides in extensive savings to taxpayers and consumers through the mechanisms it provides, we believe that it is a very good measure. So I guess it is a question of weighing up the policy levers and saying: 'Therapeutic groups, we agree, are very good policy mechanisms, but this is particularly good, too, and it is far-reaching.'

Senator TROOD—You obviously have an interest in quality, safety and price, as you say, and timely availability of drugs is an important principle, I assume, for the forum.

Ms Bennett—Yes, very.

Senator TROOD—You have heard the evidence and seen the submissions that raised doubts about whether or not these reforms are actually going to be as easy to accomplish as some of the other submissions, including the government's, say. Would the forum be troubled if in fact there were to be disruptions in relation to supply and if the reform process itself were to become far more complicated than some people seem to think it will be?

Ms Bennett—Yes, we would, fundamentally. We would be concerned if there were major disruptions to supply. As we have said, we believe that that should not be the case, because there are obligations, through the CSO and the Fifth Community Pharmacy Agreement, that should negate that kind of disruption. We would certainly want to see some monitoring of any kind of impact. If it were the case that there was anticipated serious disruption to supply then we would want to see some transitional arrangements or whatever is necessary to ensure that this does not impact negatively on consumers.

Senator TROOD—Do you acknowledge that, when we go from 160-odd drugs to whatever the figure is—and there is obviously a dispute about that—then there is potential for this to be a far more complicated administrative process than it has been so far, even in relation to price disclosure?

Ms Bennett—I am less convinced by the administrative arguments, because we already have the infrastructure in terms of the administration, because of the current 160 brands that are under price disclosure. So, really, the infrastructure should be there and it could be built on, you would expect. I suppose, for us, the issue about whether pharmacy and wholesale meet their obligations is a concern; there is always a potential for that to be a concern. But I do believe that the arrangements that are in place should negate any reason to believe that that is a serious concern.

Senator TROOD—Have you undertaken any inquiries? Have you done any studies? Has the forum investigated this to convince itself that in fact these concerns that have been raised are unrealistic concerns?

Ms Bennett—We have spoken with all of the stakeholders concerned. We have spoken with the Department of Health and Ageing; we have spoken with Medicines Australia; we have spoken with GMiA. We understand the concerns and we understand the issues. We understand that there are differences of opinion about the degree to which this might be a serious issue, and there may be some disruption in supply. We have been involved in consultations with consumers around the Fifth Community Pharmacy Agreement, and we do believe that that agreement is a substantial agreement that benefits pharmacists in this country and will, hopefully, ultimately, benefit consumers. There is a strong obligation, as a result of that significant, $15-billion deal that the government struck with pharmacists, on them to ensure that the needs of the people who use and pay for their services are met. There are significant monetary, financial, benefits to them that should ensure that that happens.

Senator TROOD—Now—

CHAIR—You have had a fair shot.

Senator TROOD—Yes, Chair. I just have one more question. The Pharmacy Guild has put this proposition regarding timing, and delaying some of the operative dates—given the fact that the bill has yet to pass the parliament. What is your view on those recommendations? Would you take the view that it is better to err on the side of caution to make sure this works effectively, or do you think that the revised MOU with the new dates is the preferable one?

Ms Bennett—I suppose ultimately we are concerned about what is in the best interests of consumers and our members. Our members have indicated that they would be concerned if there were the major disruptions to supply. So from our perspective it would be important to ensure that that does not happen. Whether that means that there are transitional arrangements put into place or whether these arrangements are monitored closely by government and acted upon, should that be the case, then we would support that.

Senator TROOD—Can I take it that you would err on the side of caution—to ensure that your principles of quality, safety and price are preserved—so that in fact if these deadlines which have now been imposed are going to create some of the foreshadowed difficulties then we would be better off putting it all back a bit?

Ms Bennett—I suppose we do not have good information, in terms that we do not know for certain that it will not be an issue. We cannot see that there should be any substantial reason to believe it will be an issue given the arrangements in place, but clearly we would want the government to guarantee that that would not be the case. We would certainly expect that pharmacists and wholesalers will act on the agreements that are in place.

Senator FIERRAVANTI-WELLS—Ms Bennett, I noticed that in your submission—and you might have heard the discussion previously about consultations—you say you were not consulted in relation to the MOU. You heard evidence earlier about the government talking generally about PBS reforms. Was yours one of those groups that were approached or were part of general discussions about the PBS reforms?

Ms Bennett—We talk regularly to the government, to the department, about PBS reform and about medicines issues for consumers. We were not specifically consulted around this. In fact, we were not aware that there was an MOU being negotiated until it was announced on budget night.

Senator FIERRAVANTI-WELLS—You and me both!

Ms Bennett—Ultimately we would always expect to be involved in those discussions because the people we represent are significant beneficiaries of medicines.

Senator FIERRAVANTI-WELLS—Following on from that, and I will not traverse the comments that Senator Trood made in the questions, given the market impact and given the consumer impacts and with the benefit of hindsight, what additional input could you have given to this process to ensure a full reflection of market concerns?

Ms Bennett—I suppose that is where we look at this as a touchstone for what value consumers might receive from this MOU, and we believe it is pretty close to the mark. If we were sitting at the table we would have raised the concerns that we have discussed today. We would have raised the concerns around ensuring that there be no disruptions to supply. We certainly would have expected close monitoring of the agreement and its impact on consumers. They are the kinds of things that we would have recommended, so they are the things that we are now suggesting be put into place to make sure that consumers do not suffer any unintended consequences as a result of this bill.

Senator FIERRAVANTI-WELLS—I guess from the consumer perspective and from your perspective you are in the ultimate position and as consumers you really do not have anything else, other than getting the best value for money—that really is where your interests lie. So to some extent you are probably the more impartial observer in this process.

One of the issues that you have raised in your submission is about the cabinet time frames. I think you are aware of evidence given at the last estimates that the time period for consideration and approval through the cabinet process has gone from six months to about an average of 10 months now. How much of a concern is that? At the moment, I think there are about 10 items currently before cabinet and some have been sitting there for up to 10 months.

Ms Bennett—Certainly it is a concern for the people whom we represent. We often hear about the real impact this has on consumers when there are these kinds of delays on drugs that they really do need. That is

why we welcomed that measure in this bill. It is important that those best endeavours will be met, but we certainly want to see a reduced time frame around consideration of those drugs.

Senator FIERRAVANTI-WELLS—Those best endeavours will have to improve and I think you are going to have to apply a lot more pressure. If we have gone from six months to 10 months then, despite provisions in this MOU, it is very clear that the government is moving in the opposite direction and not meeting the time frames that were supposedly agreed to in this MOU. I am sure the forum will be active.

CHAIR—Thank you, again, to members of the Consumers Health Forum. If there is anything you wish to comment on, we need the comments by Friday.

Ms Bennett—Okay. Thank you.

[11.42 am]

BARONS, Mr Brett Lucas, General Manager, Supply Chain and Strategy, Symbion Pharmacy Services; and Director, National Pharmaceutical Services Association

BEERENS, Ms Pattie Anne, Executive Director, National Pharmaceutical Services Association

DAVIES, Mr Patrick Donald, Chief Executive Officer, Symbion Pharmacy Services; and President, National Pharmaceutical Services Association

HOOPER, Mr Mark Robert, Chief Executive Officer, Sigma Pharmaceuticals Pty Ltd; and Director, National Pharmaceutical Services Association

CHAIR—Welcome. We have your submission. I know that you have information on parliamentary privilege and the protection of witnesses. If you would like to make an opening statement we will then go to questions. I am hoping to wrap up this section by about 10 past, so you have a sense of the time. Mr Davies, are you going to start?

Mr Davies—I will talk on behalf of the group. We will not keep you past 10 past, unless the questions are particularly pointed.

CHAIR—They could be so exciting we will all stay—you never know.

Mr Davies—Firstly, a short background on what we do. I am not sure that everybody understands what we do. I see some of you shaking your heads, so it is probably appropriate.

CHAIR—I do not think you have joined us very often in the past for these sorts of inquiries, so it is probably useful to put something on the record.

Mr Davies—We view ourselves as the heart of the industry. That is a way for you to think about us. Symbion is known as a company at the heart of pharmacy, so I use the term somewhat as of a metaphor. We push and distribute products and services throughout the industry—products pass through us. The analogy is also meant to illustrate that typically people do not worry about their heart until there is a problem. You do not think about it. It is working silently doing what it is meant to do. We do not appear in front of environments like this because we are behind the scenes getting on with the job. The sector in which we play is a fiercely competitive sector. There are no superprofits being made in this sector. We do not view ourselves as being the beneficiaries of great wealth. Our role is not particularly well understood.

What we are doing every day across Australia is ensuring that products are passing from manufacturers and suppliers through to every pharmacy not just those pharmacies that perhaps are located in major metropolitan settings. We deal with every one of the 5,000 community pharmacies right around Australia for a vast range of products. We have collectively, across the three national wholesalers, over $1.7 billion invested in our businesses. We employ approximately 3,000 Australians. We employ the very best sophisticated systems to provide a service that ultimately makes the national medicines policy possible. We actually bring it to life in the country.

Beyond pure logistics, the facilities of putting products into a shed, putting them onto a truck and sending them to a pharmacy, we play a role that I think is not well understood—that is, to help support the financing of the sector. What I mean by that is that, when we buy products and inventory from all of the manufacturers and the suppliers, they have confidence that we will pay their bills. When pharmacists order all of those products, including the very low-volume items—those products that are stocked by pharmacists only when they need them—so products that are on the PBS but are not used particularly frequently, the pharmacists have confidence that the wholesalers will have that inventory available for them. We take the credit risk that all of those 5,000 pharmacists will ultimately pay us. The value of what I will call 'working capital'—without trying to be technical—the value of exchange of money between wholesalers, manufacturers and pharmacists tallies into the billions. There is the financing role of the wholesaler—because we take title of the inventory from the manufacturer, we own it, we warehouse it, we then resell it—we take the credit risk that the pharmacist will pay it.

Senator BOYCE—That is no different from wholesaling in any other area surely.

Mr Davies—No it is not. It is the nature of wholesaling. My point is purely that some people may not understand that title of the inventory passes through us. It does not rest with the manufacturer. The financing role that we play helps pharmacists also when they open a store or when they are relocating a store. When they

are pushing into a new area we will help them with their opening orders. We give them some extended terms to allow time to get on their feet. We help them as they are going through partnership restructures even, on occasions, if pharmacists are going through a divorce, we will be there to help them. We provide, if you will, together with their own equity and with money they have borrowed from banks, the wholesalers provide a form of finance through the pharmacy industry. Balancing that up is a delicate act and pharmacy owners who take on the obligation of investing in businesses have a mix of their own borrowings, some of their own equity and, obviously, our support. The point I raise in referring to our financing role is that the changes we are talking about through PBS reform have the real possibility of impacting that fine balance of financing the sector and we will talk a little bit more about that.

Wholesalers also support pharmacists in lots of other ways. I will not go into the details this morning but we do run technology companies that support the industry. We help with programs for pharmacists to screen patients. We promote pharmacists stepping forward in their roles in their shops through training of their staff, training of the pharmacists themselves and finding ways that they can be the most successful and prosperous businesses in the marketplace.

We have four key points in relation to the reforms that are in front of government. Firstly, the reform agenda prior to the 2010 announcement had very significant consequences for the wholesale sector. I think all of the reforms, from our point of view, need to be looked at together. While I appreciate we are talking today primarily about the 2010 reform, the earlier reforms and the 12½ per cent measure, which I know you have heard of this morning, the 2006 reforms and now the 2010 reform from our calculations, as noted in our submission, tally $383 million for our sector over the life of the fifth guild-government agreement or the Fifth Community Pharmacy Agreement or $76 million per annum.

In the context of our current wholesaler profitability and that critical role we play in financing the pharmacy industry, that is a very large consequence for the sector. The scale of that impact is unprecedented. We do not have history to lean on to act as a guide as to how we might cope through it. We do not have the ability as a sector to take that cost out of our business to compensate. Ordinarily, in any other business, when faced with a major impact at the revenue, at the sales or at the top line of your business, you would go back into your business and take cost out. That would be the first thing you would do. We are not saying you should not do that. We absolutely should and we are—that is what we do every day—but we have some structural barriers to doing that. Most important is our commitment to the Community Service Obligation that we will deliver all of the PBS products to every pharmacy within 24 hours if requested. To simply hack into our costs to make the service levels lower or leaner or more efficient, from our point of view, is not possible while committed to the CSO. We are not saying the CSO is a bad thing; that is not my intention; it is just to note that is one of the issues that face us.

Our second point is that we do not believe that the full extent of the consequences on us and on our industry is understood. As part of the 2010 reform process, we learned of the changes relating to the process. We did not make specific submissions into that negotiation. It is our view that, while we attempted to engage, we were not privy to the detailed proposals. They were confidential as we have heard. Consequently, we do not believe that the full impact as it relates to our sector is necessarily included in those reform savings. That in itself may open a window to some adjustment mechanism for the wholesale sector without there being a budget consequence.

The third point is that in earlier reform negotiations, in 2008 in particular, the wholesale sector was contemplated specifically at that time. There was additional adjustment funding provided through a top-up to the community service obligation. On this occasion we see a similar consequence for the sector. An unintended consequence of the reform is the financial burden passed on to the wholesaler and we would respectfully, as we put in our submission, request consideration of adjustment again at this time.

Lastly, a point that I know has been discussed earlier today: the specific transition impacts around April 2012, when the minimum 23 per cent reductions hit, are of significant concern to us. Again, we do not have history as a guide. Although we have had prior price reductions, they have not been to the scale that is contemplated for April 2012. The way that the wholesale sector works is that we will suffer a massive devaluation of our inventory on that day. Unless we were so brave or stupid as to run our inventory to zero on 31 March and be able to restock it completely on 1 April, which is practically impossible and a fanciful idea, we will suffer a significant devaluation when the price reductions hit on that one day.

We typically try to work with the supply community to understand that there should be some support for us. It is not intended that we wear that loss ourselves—or it has not been typically. But, again, the scale is

unprecedented and we have no certainty through that period. There is no regulatory framework at this point—and there has not been in the past either—to deal with what will be a very significant one-off devaluation to us, which is not included in our submission. Our assumption in our submission is that the devaluation that will occur on 1 April is managed between the wholesaler and the supplier so the suppliers will fund that change. If that is not the case, we have a further stress on the sector.

Senator SIEWERT—I am interested in how your organisation is funded.

Mr Davies—The members pay a subscription, so it is funded entirely by the members.

Senator SIEWERT—You heard the evidence from the Consumers Health Forum around issues under the community service obligation. The point they were making is that any disruption to supply or the issues around supply should come under that process, and you have just mentioned that. How do you respond to that bearing in mind the evidence from the Generic Medicines Industry Association this morning, which was there is going to be a huge disruption to supply for, they were implying, a large number of weeks, whereas the Consumers Health Forum are saying that comes under your community service obligations?

Mr Davies—We acknowledge the need to honour all of our obligations under the CSO.

CHAIR—Mr Davies, they are your members who acknowledge that? I just want to get it clear. You are the umbrella organisation—

Mr Davies—Correct.

CHAIR—so you yourself do not have an obligation, but all your members do. Is that right? I just wanted to get that—

Mr Davies—No, that is correct.

CHAIR—So, when you say 'we', you mean your member organisations?

Mr Davies—Correct. If it would help, for a moment I will talk as Symbion. We have signed a deed with the government. It obligates us in return for payment to do certain things, and we will do everything we can to honour those obligations. The point we raise in this context is that we are facing, on 1 April 2012, an unprecedented impact on the sector. We cannot look back necessarily to what happened in August 2008 as a guide to what might happen in April 2012. In August 2008, although it was a frantic time—and I am referring to a 25 per cent price cut that occurred on 1 August 2008—we did ultimately work with the suppliers, with the manufacturers, to help the wholesaler and ultimately the pharmacist deal with the price reduction.

What I am hearing from GMIA and from others, more loosely, is that the scale of the change that we are facing in April 2012 does not necessarily assure that they will step forward in the same way as they did in the past. For the wholesale sector to absorb stock devaluations that will tally into the tens of millions of dollars on a single day puts the viability of the businesses at risk. Whether we are obligated to the CSO or not, we have to run a business to have people employed and be able to move the products around. We are juggling two very significant obligations at the same time. My point is: without the supplier community giving us commitments in advance—and there are typically two things that happen. Either the supplier community allow us access to the lower prices well in advance so we can manage our inventory carefully or they provide us with what is known as a stock-on-hand claim. On the day that the devaluation hits, 1 April, we tell them that we have 100 units of the products that are their products in our warehouse and they compensate us for the devaluation impact, because it is typically not the role of the wholesaler to wear those massive devaluations. But this time we do not have that—

Senator SIEWERT—Have you had conversations or discussions with the suppliers and government about how you handle this transition?

Mr Davies—We have not for 1 April 2012 at this point, no.

Senator SIEWERT—Sorry, I am not sure if you were here for the evidence from the guild—

Mr Davies—No, I was not; I am sorry.

Senator SIEWERT—or have seen their submission, where they were saying that although they were supportive of the bill they have concerns about time lines and they want them to shift or be changed.

Mr Davies—Yes. I am aware of—

Senator SIEWERT—I understand that changing the time lines would only help to a certain degree.

Mr Davies—That is right. The initial request is that the start date for price disclosure be pushed backwards to clear it away from a busy time for the sector, and I support that. That to me is a logical recommendation. It does not, however, tackle the financial consequences for the wholesale sector, but it does have a logical—

Senator SIEWERT—It would allow you, though, a longer lead time to negotiate some sort of more practical solution with both the suppliers and the government?

Mr Davies—On the delay in the price disclosure, I will just quickly clarify: the price disclosure has very little consequence for the wholesalers. Administratively, we do not sit in the middle of that process. The manufacturers, the suppliers and the pharmacists need to aggregate the information. From our point of view, what is critical is what happens on 1 April when the devaluation actually hits us and what happens really from February next year forward on the dollar revenue that is passing through our businesses. That delay does not change that.

Senator FIERRAVANTI-WELLS—I will take you to your submission. You made a point about the reduction in wholesaler remuneration. When did you first become aware of the MOU? Did you read about it on budget night as well?

Mr Davies—We were alert to industry noise that there was something happening and we read it about it in the budget papers ultimately.

Senator FIERRAVANTI-WELLS—You heard earlier that I asked questions about the general reform process. Were you part of that? Were you invited to participate in general submissions about PBS reform?

Mr Davies—In relation to earlier reforms, so in relation to 2008, we had some ongoing dialogue with the department and they were certainly open to submissions from our industry association and to helping us understand the process and the ramifications of it. Our anxiety was that the true impact of those earlier reforms was not fully understood. In relation to the 2010 negotiations, we were not invited to make submissions. We were not privy to the details of what was being negotiated. My understanding is that it was in confidence between others.

Senator FIERRAVANTI-WELLS—You may have heard evidence earlier this morning from GMiA and also from the Consumers Health Forum about general discussions about PBS reform. My question to you is: were you invited to participate in that at all, separate to the MOU negotiations? I appreciate you were not a party to that. Is your answer to that no?

Mr Davies—No, we were not invited to submit.

Senator FIERRAVANTI-WELLS—Looking at it from a global perspective, you have such an involvement. You are part of the process that ultimately results in every script that is delivered here in Australia. Is that a fair assumption?

Mr Davies—There are some that go directly from manufacturer to pharmacy that bypass the wholesale channel, but it is a relatively small percentage.

Senator FIERRAVANTI-WELLS—We are talking—

Mr Davies—I think eight or 10 per cent.

Senator FIERRAVANTI-WELLS—the figure that I used before.

Mr Barons—We would be 90 per cent or 95 per cent.

Senator FIERRAVANTI-WELLS—At the bottom of page 1 of your submission, you say:

All PBS Reform price reductions have an unaccounted for and unintended impact on wholesalers.

Have you quantified what you think that consequence will be?

Mr Davies—The dollar consequence of all of the reforms that have been announced or proposed to date, and I keep referring to the next five years, so five years of what we call the Fifth Community Pharmacy Agreement, we think for the wholesale sector is $383 million.

Senator FIERRAVANTI-WELLS—And that is just taken straight off the top because of this automatic reduction that is applied to you?

Mr Davies—That is right.

Senator FIERRAVANTI-WELLS—Can you pass that on?

Mr Davies—It is my opinion—I speak on behalf of Symbion, rather than everybody; Mark might have a personal view—that as a business we interact with probably 3½ thousand pharmacies every day, and roughly 2½ thousand of those we would call our front line or our first line customers. I do not see that there is this superprofit lying around to be paid to us if we changed our pricing to community pharmacists. When we try to tweak anything in our trading term relationship with the customer, particularly with the younger pharmacists who are buying their businesses, who have debt, who are geared to run their businesses, there is an instant push back—as you would expect, that is the nature of the rough and tumble of commercial enterprise. But the scale of these changes is not trivial. These changes are enormous. It is $76 million per annum. I do not see that there is $76 million waiting to be passed through to the wholesaler from the pharmacies.

Senator FIERRAVANTI-WELLS—Can I just reduce this to a simple proposition—that is, you are going to get to a particular point where the wholesalers cannot absorb the costs and they are going to have to pass it on and then, if the pharmacists can deal with that, they can, if they cannot, well, that is their issue. Is that a simple—

Mr Davies—Again, I would just talk about—

Senator FIERRAVANTI-WELLS—I am not saying that you will, all I am saying to you is that that is the most reasonable scenario. So ultimately what that will result in is: either the pharmacists and price variations, or a pharmacy in a particular area will no longer be able to function and, therefore, will have no choice but to shut down. These are potential consequences.

Mr Davies—That is my view, absolutely.

Senator FIERRAVANTI-WELLS—So ultimately the person who dips out in all of this is the consumer.

Mr Davies—If there is a serious shock to the supply chain that results in pressure on pharmacists being unable to dispense the medicine, you are right.

Senator FIERRAVANTI-WELLS—How many wholesalers are in the pharmaceutical space, if I can put it that way?

Mr Davies—There are three national wholesalers and there are two state wholesalers, all of who participate in the community service obligation. There are half-a-dozen other, very small state based cooperatives.

Senator FIERRAVANTI-WELLS—So we are talking a very limited pool and with little scope for these costs to be passed on in a competitive environment, if I can put it that way. It is a necessary function and it therefore has to take its course?

Mr Davies—I look at it this way: the wholesale model has been chosen by government to deliver the national medicines policy. Free enterprise is invited to participate in the sector. If it is not appropriately funded, free enterprise will do what it does: it will have to collapse, aggregate, change in some way. At least two of the three national wholesalers are publicly listed companies. It is available for people to look at. It is not a sector that can turn into itself and take these kinds of impacts without consequence and that consequence is somewhere through that supply chain.

Senator FIERRAVANTI-WELLS—So, not having been consulted before the MOU, when you became aware of the MOU subsequent to the budget, did you approach government to voice your concerns about the possible consequences? Can you tell me a bit about that?

Mr Davies—Yes, we did. Perhaps Pattie can just refresh my memory on the exact process.

Ms Beerens—There were rumours about potential further PBS reforms on top of the existing 2006 reforms since before the previous budget. We have written to the minister on a number of occasions and have met with the department and others. We have also written to the minister since the budget announcement stating that the sector is struggling with the current range of reforms. It is particularly concerned about this additional range of reforms, because we have not had the opportunity to get any transition arrangements in place and funding like we arranged to have in place with the earlier reforms.

These reforms were negotiated in the context where you had the guild, which could manage their issues in the context of their agreement and where the manufacturers obviously worked it through with the MOU. The wholesalers really did not have a channel through which to deal with their issues with transitioning in this instance, whereas they had in the last instance.

Senator FIERRAVANTI-WELLS—Have you had a response?

Ms Beerens—Not that I recall. I do not believe so, but I would have to check that.

Senator FIERRAVANTI-WELLS—You have outlined to government the potential consequences and been fairly forthcoming in relation to that?

Mr Davies—Yes, we have.

Senator FIERRAVANTI-WELLS—And it has, in effect, been ignored?

Mr Davies—We have not got a response that we feel is satisfactory—no resolution, no change.

CHAIR—Mr Davies, can I clarify: do you have a response, not whether or not you are happy with it? Ms Beerens indicated she had not had a response. I want to clarify.

Ms Beerens—I will check the actual status of the response to the letter we sent post the budget.

CHAIR—Good.

Ms Beerens—Prior to the budget announcement we did get responses and opportunities to meet. We have repeatedly said the same thing in terms of the concerns about the current measures and the ongoing impact and our concerns about any future measures, if they are to be introduced.

Senator FIERRAVANTI-WELLS—When you raised those concerns about existing reforms, at no stage were you advised that there was an MOU about to be made or in the offing that would have further impact on your operations?

Mr Davies—No.

Senator FIERRAVANTI-WELLS—Since you wrote your letter, after the budget—you are going to clarify whether you have had a response.

Ms Beerens—I will clarify the nature of the response.

Senator FIERRAVANTI-WELLS—If there has been a response.

CHAIR—Can I also have clarified the way that that response was then circulated within the organisation, because there does seem to be a bit of confusion there?

Mr Davies—Certainly.

Senator TROOD—On page 9 of your submission you have some recommendations. It refers to some dollar figures—$34 million in relation to the 2006 reforms and $24 million in relation to the 2010 reforms. But I understood you to say, Mr Davies, that the point about the devaluation, as you are calling it, in April is not in the submission.

Mr Davies—That is correct.

Senator TROOD—So my question is: do these figures now represent your view as to the kind of compensation that is necessary to accommodate your concern about April?

Mr Davies—They are related but separate. So, regarding April 2012, the assumption when we put this paper in was that we will be able to negotiate with the supply community to deal with the one-off devaluation to our inventory, that we will find a way through that. If we cannot—and, as we are hearing in submissions to today's enquiry, the supply community is also very anxious about the cut-off date—then this submission is, if anything, undercooked in terms of the consequences.

Senator TROOD—How undercooked is it? How raw is it?

Mr Davies—We would probably need to take that on notice, but the likely devaluation impact for Symbion alone will be somewhere near $10 million on that one day. So, simplistically, you can multiply that by three.

Senator TROOD—Have you begun discussions with the suppliers?

Mr Davies—We have not had in-depth discussions yet.

Senator TROOD—But have you had any indication of whether they are likely to be willing to accommodate the concerns you have?

Mr Davies—Using the generic association as an example, the corridor conversations are not particularly encouraging at this point. I have not had, through Symbion, detailed discussions on the topic with the supply committee yet. I think most of us have thought that we need to be clear on what the dates are and what the final form of this legislation is before we go into too much detail on that.

Mr Barons—We have traditionally had the conversation six month out; so, at that point, we would ramp up the discussions.

Senator TROOD—At page 8 of your submission, under 'Timing of pricing changes', you say:

The PBS Reform arrangements do not provide a sustainable arrangement for the management of price reductions within the supply chain.

Is that sentence a reference to the matters that you have been addressing this morning? In particular, is it a reference to the problem in relation to April, or is it a reference to something else?

Mr Davies—It is in relation to April 2012.

Senator TROOD—It is at reference specifically to April?

Mr Davies—Yes.

Senator TROOD—Do you have a view on the timing of the introduction of this legislation in light of your particular concerns?

Mr Davies—Can I say never? No! On the timing in relation to the start of price disclosure—I think the government are currently proposing 1 December—I agree with the guild that that date should be pushed backwards. That has very little consequence for me or for our member organisations because it is typically supplier and pharmacist information.

Senator TROOD—But in your professional assessment?

Mr Davies—My knowledge of the industry is that that would be a dangerous time to bring in the implementation. I support the guild's position on the revised timing for that.

But **Senator TROOD**—So you support the guild's position in relation to all of those steps they have introduced?

Mr Davies—I support their proposed delay to the start of that. It does not ultimately address the financial consequences.

But **Senator TROOD**—No, I understand that point. But I am interested in your view in relation to the timing.

CHAIR—Thank you. We would like to get your answers about the consultation on notice. If we require any other information, you will be contacted this afternoon. Thank you for your submission and for your attendance.

Proceedings suspended from 12.14 pm to 1.10 pm

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

HENDERSON, Mr Nick, Acting Assistant Secretary, Policy and Analysis Branch, Pharmaceutical Benefits Division, Department of Health and Ageing

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

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

STUART, Mr Andrew, Acting Deputy Secretary, Department of Health and Ageing

CHAIR—I welcome representatives from the Department of Health and Ageing. You all have information on parliamentary privilege and the protection of witnesses and evidence. The essential paragraph for public servants is: as departmental officers you will not be asked—Senators!—to give opinions on matters of policy, though this does not preclude questions asking for explanations of policy or factual questions about when and how policies were adopted.

We have your submission, thank you very much. I invite any one or all of you to make opening comment and then we will go to questions. I know that you have been listening to the evidence this morning. There are a number of key areas that we would like to cover if possible. When we get through the opening statement, Mr Learmonth, we might go issue by issue to see whether we cover those key areas, if that is okay with you.

Mr Learmonth—Sure.

CHAIR—Mr Learmonth, are you going to kick off with an opening statement?

Mr Learmonth—I will if I may. I am conscious of the committee's time but I would equally, having listened to some of the debate this morning, like to get a few things on the record and bring us back to some fundamentals. I intend in some ways to borrow from the first witness in going through a bit of the 'what' and 'why' and some of the fundamentals of the approach that has been taken.

First of all the why—why this round of reforms? There are several things. Firstly, the PBS continues to grow. In the last two years the growth rate was above nine per cent. It will be above $9 billion this year. It is a very large and significantly growing program. There is debate about how much the 2007 price disclosure reforms may or may not yield. There are a number of estimates. One thing is clear from our perspective: we are already at a level of expenditure now, after those reforms, which is in excess of where we thought we would have been without them. From our perspective that really illustrates the growth. We are right now above where we thought we would be without the PBS reforms. So, whilst they have had an impact, there is significant growth in the PBS.

Secondly, in relation to the 2007 changes, whilst they would largely get us to the same end point there is no new policy in this; it is merely the acceleration and deepening of what was already there. It was slow to work, and the principal reason is that for price disclosure, which is the principal agent of this, to operate under the 2007 reforms it required a trigger, and that trigger for a medicine was the listing of a new brand. If we take, for example, simvastatin, which is sold at much lower rates in the UK and other markets compared to what we pay in Australia—

CHAIR—Mr Learmonth, picking up Senator Fierravanti-Wells's point: for the millions of listeners to this inquiry, what particular drug is that one?

Mr Learmonth—Simvastatin is a cholesterol-lowering, a lipid-lowering, drug. It is very common; high volume. We now pay an awful lot more here for that than other markets do.

It is also the case that there are 17 brands of simvastatin currently on the Australian market. It is a very mature and saturated market for that particular medicine. It seems unlikely that in the near future another brand would list, so the circumstance where we pay many multiples of the world price for that drug would seem to persist. It was slow to act.

Senator BOYCE—Could we have the figures? You are talking many multiples; what do you mean?

Mr Learmonth—For a 40-milligram tablet of simvastatin the PBS listed price is $38.03. In the UK it is $2.85.

CHAIR—Two dollars or two pounds?

Mr Learmonth—Two dollars, eighty-five—the Australian equivalent.

Senator BOYCE—That is quite a few multiples.

Mr Learmonth—Yes; that is multiples. It is—what?—16 times?

Senator CAROL BROWN—What was the total PBS cost for that drug in the 2008-09 year?

Ms Platona—$165 million.

Mr Learmonth—$165 million.

CHAIR—You just happened to know that, Ms Platona, did you?

Mr Learmonth—She did. If I might continue—

CHAIR—Sorry; yes.

Mr Learmonth—So, again, the issue with price disclosure as currently constructed is that it is slow in its impact, and in the meantime we are paying above world prices for many of these off-patent medicines in the commodity market. So, in all of that context, if we still have a rapidly growing PBS there is still an obligation to look to what we can, in terms of sustainability. If we are paying more than, arguably, we ought to, in terms of world prices for these medicines, and if we can effect some change without impacting on access, quality or other important fundamentals of the PBS, then it is only reasonable to contemplate that.

Secondly, I will turn to the impact on manufacturers and make a few brief points. The first is that price disclosure, which is the core of this, is not an arbitrary price-cutting mechanism; it is a price-taker. All it does is to ensure that the price the government pays reflects at what price those manufacturers have already chosen to sell their product into the marketplace. Above that it is actually an average weighted price. So it is cushioned. It enables some competition, and it ensures that some, perhaps unusual, effects in small parts of the market do not actually dominate. It is a very gentle way of reflecting a market price, using the average weighted price.

Next, nothing really changes the fundamentals of the ability of the generic sector to compete. Nothing in this changes their ability to bring a new generic product to market, and nothing in this changes their capacity to compete on a level playing field with the originator medicines in the off-patent market—that is, on price. It is a very price sensitive market. They are still able to compete on price; nothing changes there. It is a level playing field.

Finally, in terms of the overall impact on manufacturers, it is clear, on any analysis, that their market is growing. Firstly, the overall PBS is growing. Secondly, their share of it is growing—it has gone from 27—

CHAIR—Mr Learmonth, I take it that this is the generics' share?

Mr Learmonth—Yes, these are the generic manufacturers within the off-patent sector. The overall market is growing. The share that the generic manufacturers have of that market is also growing. It has gone from 27 per cent to 34 per cent in the last five years or so. And, as I think a number of witnesses have said today, there is a large number of medicines which are going to come off patent in the next few years. The experience internationally is that generic manufacturers quickly pick up a significant proportion of that market for new drugs coming off patent. So their market is growing and their share of it is growing.

Senator BOYCE—Could I just clarify: when you say 'generic manufacturers', do you mean originator companies—

Mr Learmonth—No, I mean 'generic'.

Senator BOYCE—who make generic products, or strictly only generics?

Mr Learmonth—Strictly the generic copies—their share of the off-patent market is growing and the total size of the market is growing.

Let me turn now to consultation. The department had discussions of one form or another with a number of players, starting last year, about the general issue of PBS sustainability and what might be done in the lead up to considering measures for the following budget. As I said, we had discussions with a number of players and they went in different directions. For example, the discussions with Medicines Australia, whilst, I think, initially difficult, ultimately proved over the long term to be fruitful, and there was some mutual accommodation that resulted in an agreement or an MOU. In the case of the Pharmacy Guild, similar discussions about sustainability—again, protracted negotiations—resulted in the Fifth Community Pharmacy

Agreement, which saved just over $1 billion from forward estimates as a contribution to the sustainability of the PBS.

In the case of GMiA, it is true that, whilst they were not consulted on the MOU per se, when it was announced the key elements at issue—in other words, the savings, the price disclosure—were indeed in discussion between us and them over a number of meetings that we have detailed, and it would be true to say that we were extremely clear on what their view was on those things. Their view was that we should, rather than deepen or accelerate price disclosure, eliminate it. We are also clear on their other views about how we should increase generic market share by asking consumers to pay more for branded off-patents. So it is true to say we were very clear about what GMiA thought of price disclosure as a proposition in these discussions. Those discussions, at their request, remained confidential, just as the discussions with Medicines Australia remained confidential.

I will now turn briefly to the issue of complexity and administration around price disclosure. Let me say first that we think these companies know what they sold their product for; if they do not, it is unclear to us how they manage to issue accurate invoices to their customers. The reality is that these are sophisticated companies. They know what happens to their stock and they know what they sell their stock for. They understand what happens to the movement of their stock and prices. They have IT systems to deal with all of that—to manage stock, to invoice customers, to manage receivables and all that sort of stuff.

Price disclosure already exists—it has done since 2007, when the reforms came in—and it is unclear to us that the move from disclosure that affects a smaller number of medicines to disclosure that affects a larger number of medicines give you some sort of commensurate increase in the problems. It seems to us that if you have a system in place that will deal with price disclosure for some of your products, it is not that difficult for the same system to accommodate all of your relevant products. That said, we are working with them to help improve the existing price disclosure system. We have got a price disclosure working group.

Senator BOYCE—Who is 'them'?

Mr Learmonth—We are working with the industry. There is a working group on price disclosure that includes Medicines Australia, GMiA, NPSA and AusBiotech. We have been looking at ways to improve and streamline the current system by reducing the amount of reporting to accommodate the various systems that they themselves use to track through inventories and prices and to generally ease the burden as much as possible, and I think that has been quite productive.

Let me close by saying that, overall, in terms of impact on other key parties, there is no impact whatsoever from these reforms on clinicians—on their ability to prescribe and their ability to direct a patient to any particular medicines. From the patient's perspective, as both individual consumers and taxpayers their access will not be compromised and the quality will not be compromised; but, wearing both hats, they will pay less.

Senator SIEWERT—I am still confused about what percentage of the market the companies under Medicines Australia have and what percentage of the market the GMiA companies have in terms of cost and volume. Can we go through what you understand that to be and then I will compare that to the other answers I have had this morning.

Senator BOYCE—Before you do that, can you confirm that your figures cover every medicine that is prescribed in Australia?

Mr Learmonth—Yes, I will be able to pick that up. I have listened to the question and will answer it the best I can.

Senator FIERRAVANTI-WELLS—It would be good if we could start with the premise that we provide them with 180 million scripts per annum. Thank you.

CHAIR—Seeing as we are all having a comment, there is a direct quote from GMiA—and I know that someone in your department will have heard it—that 'government has an imperfect view of the market'. So, now that everyone has given you directions about what you need to say, can we go to the data?

Mr Learmonth—Let me start by saying that I think everyone has got an imperfect view of the market because there is no one source. We will have a perfect view of the market when we get disclosure under co-pay dispensing, but right now everyone has an imperfect view. We have a perfect view of what we pay for, which is the overwhelming majority of the PBS. So there are a couple of things to say about this issue of data and market share in relation to the off-patent sector. On our reckoning, Medicines Australia companies have

just under 60 per cent of the market by volume and, off patent, GMiA has around about one-third—I am sorry, not by volume but by price.

Senator SIEWERT—So that is by price?

Mr Learmonth—Yes, I am sorry, it is not by volume; it is by price. There are a number of companies who are members of neither but who also contribute to small but meaningful share of that. It is imperfect because it does not include under co-payers, and on that I would say a couple of things. Under co-payers represent, I think, about 18 per cent of total volume on industry surveys, so, on any reasonable assumptions of relative market share, it is hard to conclude other than that Medicines Australia continues to have the largest share by price. Equally, when it comes to the impacts of PBS reform, it seems to be a reasonable assumption that those who have the majority of the sector by price will also have the majority of the impacts of price cuts. So, in that sense, that is our view. It is imperfect but—

Senator BOYCE—But would that not also depend on the proportion of your overall business that these products that are having their prices affected make up?

Mr Learmonth—Absolutely. Individual companies will have different footprints in the on- and off-patent markets. Some will be exclusively one, some will be exclusively the other and some will span. But in the context of a discussion about representative organisations who, as I think someone said earlier, have skin in the game, from any reckoning we can do, based on any data that we have, Medicines Australia represents the majority share of the off-patent sector by price and, thus, the majority of the impact.

Senator SIEWERT—Have you done this in terms of volume? Does it automatically translate to volume?

Mr Learmonth—It does not.

Senator SIEWERT—No, that is what I thought. Do you have them by volume?

Mr Stuart—By script volume?

Senator SIEWERT—Yes.

Mr Stuart—Innovator companies represent 48 per cent; GMiA members, 43 per cent; and other generic, nine per cent.

CHAIR—Mr Stuart, I just interrupted Senator Boyce's listening to your answer. Would you mind repeating it.

Mr Stuart—I will say those numbers again, and then I will also explain why I think, as David was saying, the expenditure numbers are actually more relevant. The volume numbers: are 48 per cent for innovators.

Mr Learmonth—That is Medicines Australia.

Mr Stuart—That is Medicines Australia members; GMiA members, 43 per cent; and other generic, nine per cent.

CHAIR—I take it that that adds up to 100 per cent?

Mr Stuart—Yes.

CHAIR—Good. I did not want to do the math, and I take it that that was a full picture.

Mr Stuart—That is right.

Senator FIERRAVANTI-WELLS—Mr Stuart, what would helpful would be a chart or a table where you put this down. Senator Siewert has asked this question, and I have asked it in different ways. Is there something that is simple, that says it to us in that way but also tells us where the deficient information is—that is, where the gap is—so that we know what we are actually dealing with? Could that be done both in volume and in scripts? Percentages are one thing, but 180 million scripts is certainly a lot of scrips to deal with. That really would be helpful.

Mr Learmonth—We can provide that easily.

Mr Stuart—As to the logic about expenditure, you have to think about the marketing. There are two separate sectors: one is formerly on-patent medicines which are now off-patent and which have a brand name, where the owners of those brands are competing in the market with generics. They are part of the commodity market now but are still relying heavily on their brand name and are trying to charge a premium. They are trying to charge more and give lesser discounts by trading on their name. Also in the market are generic makers who are trying for low-cost, high-volume operation and who are probably selling the same medicine, the same drug, with a higher discount in order to gain market share. So it stands to reason that, when you

implement price disclosure, the first group of medicines will experience a larger price reduction than the second group of medicines when we move to the average disclosed price.

Senator SIEWERT—In other words, they will drop the premium?

Mr Stuart—They will have to cop a larger price reduction.

Senator BOYCE—Why?

Mr Stuart—Because they are in the market selling for more than the generic makers.

Senator BOYCE—But they would presumably argue that their brand makes it worth more and that people who have been familiar with this product for many years, without other activities going on to make them want to switch to generic, will continue to prefer the brand name that they know.

Mr Stuart—But the government now comes along and calculates the average weighted disclosed price and says: 'Okay, we're now going to drop the price for all of you. For the previously on-patent and for the new generic entries, we are going to drop the government price to a new price and we're going to pay that to all of you now.' That is going to be—

Senator BOYCE—But if that is an average then it is higher because of the premium, isn't it?

Mr Stuart—The point I am making is that the average is much more likely to be below the price that the originator makers were selling for and, therefore, they are much more likely to experience a significant price reduction.

Senator TROOD—Mr Stuart, let us allow that that is correct. Let us say they experience a price reduction. But if they still have market advantage by virtue of the fact that they continue to sell large volumes then doesn't that offset any hit that they take because of the lower price?

Senator BOYCE—They suffer less comparatively, I guess.

Mr Stuart—They are rapidly losing market share at the same time because the experience is that within two to three years of a generic entry, market share for the originator drug has fallen to about 50 per cent. At the same time as the price is falling for them, their share of the market is falling as well.

Senator BOYCE—But 50 per cent of the market where perhaps you have four or five competitors who are much smaller is still very significant, isn't it?

Mr Stuart—I am not arguing with that.

Mr Learmonth—It is not that they do not have an unsustainable share of the market left, it is that they have a significant impact on both the loss of market share and price. The ability of companies to sell into the supply chain rests heavily on the discounts that they can provide to influence people to stock their brands. So people can who come in and provide a medicine cheaper have an advantage.

Senator TROOD—On the subject of share, on data, Mr Learmonth, on page 14 of your submission makes reference to this problem of copayment. You seem to be saying you do not have any data in relation to copayment. Is that right? And that your calculations about the share in the market are based on a calculation without taking account of those sales which are at copayment or lower. Is that right?

Mr Learmonth—No, that is only partially correct. It is true that we do not have price data about under copayment, but by definition it is low compared to other things because it is under copay compared to over copay. We have perfect knowledge about what is above copayment because we pay for it. It is something like over 80 per cent of the total volume, so we do have a pretty good idea from industry surveys and sources as to what the volume of under copayment transactions are and on any reasonable assumption about the share between originator and generic companies their share of that under copayment segment. We still cannot do anything but conclude that Medicines Australia companies have the lion's share by price—and by volume too.

Senator TROOD—I am not quite sure why you make that assumption if you do not have the statistical information you need to inform that assumption.

Mr Learmonth—I am saying we do have enough statistical information in order to make an assumption. We are making an assumption because the data is not perfect, as I said. We know exactly what happens to 82 per cent of the market that is over copay. Under copay is, by definition, very small in terms of price. If you make some assumptions about relative share of one sector versus another, about the generic sector versus the originator sector for that under copay material, you can extrapolate from there.

Senator FIERRAVANTI-WELLS—Does that fit? Have I misunderstood you? If you are saying 82 per cent are over copayment, that means that it is 18 per cent.

Mr Learmonth—Which is shared between the generic sector and the originator sector. It does not all go to one. They equally compete in that space.

Senator TROOD—Mr Learmonth, I do not think anyone is arguing that it all goes to one, but GIA is certainly arguing that they have a greater proportion of that under copayment figure, and as a consequence of receiving that they have a greater proportion of this market than anybody seems to be prepared to allow.

Mr Learmonth—Senator, I guess we are arguing about—

Senator TROOD—Just let me finish this. As a consequence of them having this large amount of this market, their 30 per cent, which everybody seems to be dismissing as being relatively insignificant, in fact is added to—

CHAIR—Senator, I am going to pull you up again. I repeat: it is your assessment that people are dismissing this.

Senator TROOD—I am happy to live with my assessment.

CHAIR—If you add that to your statement.

Senator TROOD—Of course. The assumption that seems to be made is that 30 per cent, which seems to be acknowledged as a figure, is by some definition modest—those are my words—but, if you then add that agreed figure to the under co-payment figure, it becomes a more significant figure by any definition and it certainly gives you so-called skin in this market.

Mr Learmonth—I am not going to describe whether I think the share is significant or otherwise; what I will say is that no-one has perfect data about that 18 per cent. We are talking about how that 18 per cent—that small part of the total transactions—is actually apportioned. There are three players who will share in that space: the GMIA companies, the originator companies and the non-member companies. They will each have part of that 18 per cent.

Senator TROOD—That is your assumption.

Mr Learmonth—Well, there is no data.

Senator TROOD—The evidence from the GMIA is that they have something in the vicinity of 50 per cent of that figure, as I understand it. I do not think we have had that evidence contradicted elsewhere. That adds nine per cent to their figure anyway, so we are up at—

Mr Learmonth—And another nine to the others, I guess. It does not really change the overall conclusion, does it, about proportions.

Senator TROOD—No, but what it does change is the overall percentage of the overall market, and that means that the suggestion that the GMIA has a relatively modest 30 per cent is in fact inaccurate.

Mr Learmonth—It still has to add up to 100 per cent.

Senator TROOD—I acknowledge that.

Mr Learmonth—If they have half of that 18 per cent, everyone else gets the other half. If they started off with a dominant share, they are going to keep having a dominant share.

Senator FIERRAVANTI-WELLS—But you made an agreement with one entity. This is what this is really all about—you made an agreement with one entity to the exclusion of other entities. The point that Senate Trood is making is that those other entities that were not at the table are a portion of the market. Senator Trood is submitting that it is a reasonable portion of the market, but, on any reading, they are not party to an agreement but do have a share of the market and were not consulted. That is what this is really getting down to.

Senator CAROL BROWN—I would like to respond to Senator Fierravanti-Wells's comments. This seems to be one of the major issues to have emerged today. GMIA has said that there was not really any meaningful consultation. I would like the department to take us through the consultation that it had with GMIA. I assume that you went to them and the other players in the industry and asked for them to come up with some savings.

CHAIR—I am going to allow that flow of the debate on the basis that the data issue had moved through Senator Fierravanti-Wells into the reason that data was so important and now to the consultation that came out of that. We have finished on data and we have now moved on to consultation.

Mr Learmonth—This was in the period in the lead-up to the budget this year, when we were giving some thought to how to improve the sustainability of the PBS. We did not start that process with any particular fixed ideas, by any stretch. We did not start the process with a notion of an MOU on agreement—indeed, that was not our suggestion; it came late in the piece.

We started the process having some pretty open-ended discussions about how we could make the PBS more sustainable—we did that with a number of different parties—and, as I say, they progressed differently. In the case of the Pharmacy Guild, we undertook a process that was going to happen anyway as it is mandated: the expiration of the Fourth Community Pharmacy Agreement and the negotiation of the fifth. This discussion played out in that context. The result was that, as I said before, we came up with a pharmacy agreement between the government and the guild where the guild agreed to take, from memory, $1.006 billion off forward estimates as a contribution to sustainability. We worked very closely with the guild on that.

In the case of Medicines Australia, we had a discussion over months that started off with the same general proposition: how can we make the PBS more sustainable? Clearly we would look to what we already have by way of price disclosure and the other framework as a good starting point for discussion. I think that if I were to characterise the discussion with Medicines Australia, I would say that it was a bit like grief, denial and anger. It started off with a discussion about why we would still need it and the whole issue around the 2007 reforms and how they played out in terms of the sustainability in the future of the PBS. There was a degree of acceptance of the need for us still to look to more, so the discussion then turned to, 'Well, what can we do?' There was a process that led ultimately, very late in the piece, to the notion of an agreement—that is, the MOU that was struck.

In the case of GMiA, again we had a range of discussions. Some of them came off the back of submissions that GMiA had put in before about various ideas, and we talked about sustainability. There were a number of meetings that we detailed in our submission. I would add that no meeting was ever refused—it all was opened to GMiA—but I could not really characterise the way discussions evolved with GMiA as a negotiation in the same way as I could with others. We put our view that we were looking for sustainability, and GMiA made their views extremely clear on what they thought about the notion of price disclosure and any further saving. In other words, they did not really want to be a party to that. They did have some other ideas that were fundamentally about increasing competition. From our perspective, there would be two things to say about that. One is that competition generated by asking for consumers to pay more for the same product was not going to be something that was attractive and, as I think Ms Lynch said earlier—

Senator CAROL BROWN—That concern was about paying more for the originator company off-patent.

Mr Learmonth—Correct; but off-patent, yes.

Senator CAROL BROWN—So their competitor—

Mr Learmonth—Same product. Yes, that is correct. The proposition was that consumers would pay $5 more for a script that came from their competitor-originated off-patent as opposed to a generic off-patent. As she acknowledged in her testimony, it was made very clear to Ms Lynch that the government would not support that, so it is not as though there was not an exchange of views on those things; there very clearly was. In relation to the other measures to generate competition, there was some exchange. In looking at them, part of how we responded was to ask ourselves, 'Well, what benefit is the competition?' That is part of the issue—where does the benefit of competition lie? So if you were to do things that generate competition—competition in this context kind of means market share for GMiA, and the benefits of that competition or market share essentially remain private; in other words the profit derived up and down the supply chain from heavy discounting rather than the public sharing in some of that benefit of competition by taking a share of that discounting—it was going to be less attractive in terms of the sustainability of the PBS. So those discussions ultimately were not fruitful.

Mr Stuart—So what we were looking at was a proposition: 'GMiA members should have higher volume and higher market share. Please could we have a discussion about consumers therefore paying more for the products of our competitors which are essentially the same?' But we did not think that made for very good policy.

Mr Learmonth—And this was in a context where they were getting those things anyway. The PBS is increasing their share if it is increasing.

Senator CAROL BROWN—So when you ruled out what you described as their 'key ongoing proposal' about the extra payment, what happened then? Did they just opt out of the whole consultation process?

Mr Learmonth—I think part of the reason that we found it a little difficult was that we could never move beyond that. We wanted to talk about sustainability and they wanted to talk about their propositions, and we could never manage any sort of discussion beyond that. They stuck to their guns, basically, about what they wanted and we could not generate a discussion about alternatives.

Senator CAROL BROWN—Any reading of the various evidence that we have received here is that GMiA had somewhere between 34 per cent and 50 per cent of the generics market, so I am just surprised that they seem to have opted out of this process.

Mr Learmonth—I do not know that it would be fair to say they opted out of it, but clearly they did not engage beyond repeating their propositions. Other parties had ideas initially. We had ideas initially. None of our original ideas survived untainted. We had a genuine engagement, we moved along and ultimately we had an agreement. We did not sense any preparedness from GMiA, for example, to move off implacable opposition to price disclosure even as it stood let alone doing anything more with it.

Senator CAROL BROWN—So was the pricing disclosure extension from what it currently is to what we have before us now put to GMiA?

Mr Learmonth—Not in detail. I am not even sure it existed in that particular form at the time. This developed over some months. Certainly in our minds we thought we would do more price disclosure, particularly in terms of acceleration, given how slow it is to bite into those existing large margins.

Mr Stuart—I think the real bottom line here is that the department had discussions with a range of parties and we listened very hard and we understood their views very well. That was certainly the case in relation to GMiA. We respect GMiA. We see them often. We talk with them about policy. We met with them at least six times at a very senior level during the relevant period and we fully understood their views and they had a good opportunity to represent them to the department.

Mr Learmonth—And to the minister. The minister was party to that. She personally met with them and understood their views as well. It is not that they were not heard at the highest level.

Mr Stuart—On the question about the MOU and consultation on the MOU, the MOU was not something for consultation. The MOU was the outcome of a set of confidential discussions with one party which ended up simply putting into text that point we had reached in discussion with them. Had we reached a point in discussion with other parties it would be open to think about how that might have been expressed. But the full expression of the government's position here in the end is not so much about the MOU, which is about a negotiated arrangement and an exchange of views with one party, namely Medicines Australia. The government's expression of what the government is doing is in the budget and in the legislation.

Senator TROOD—Except, Mr Stuart, that the legislation is essentially founded on the contents of the MOU, isn't it?

Mr Stuart—The MOU reflects a statement of mutual intent that we would each attempt in that space.

Senator TROOD—But the legislation is based essentially on the provisions of the MOU.

Mr Stuart—The legislation and the MOU both express what the government was willing to countenance in terms of policy.

Mr Learmonth—It is within the government's prerogative to bring forward that legislation with or without an MOU.

Senator TROOD—The legislation is a reflection of the contents of the MOU, isn't it?

Mr Stuart—I think both are an expression of government intent.

Senator TROOD—And you did not tell GMiA that you were negotiating an MOU, did you? You did not inform anybody from GMiA that you were negotiating an MOU with an organisation with which they are in competition.

Mr Learmonth—The consultations with Medicines Australia were just as confidential at their request as were the consultations with GMiA, which were also confidential at their request.

Senator TROOD—So Medicines Australia said, 'We don't want you to tell our competitors that we are negotiating and MOU with you'?

Mr Learmonth—I would not characterise it like that. They asked for confidentiality—

Senator TROOD—And you did not feel obliged as the government of the Commonwealth of Australia to tell a competitor with a very large piece of skin in this particular market that, 'We are in fact engaging in a course of action that is going to be detrimental to your interests.'

Mr Learmonth—In the core of the MOU insofar as the financial impact goes we were extremely clear on what the views of GMiA were.

Senator TROOD—I hope you were clear. I hope I was speaking clearly. Whether or not I embrace their proposition in relation to the way in which the pricing matter proceeds, the fact is that you did not tell them that you were negotiating an MOU with their competitors, did you?

Mr Learmonth—Senator, as I said, the consultation with Medicines Australia was confidential in the same way that the discussion with GMiA was confidential.

Senator TROOD—So you conspired not to tell them.

Senator CAROL BROWN—That is just silly.

Senator TROOD—Well, what is it? If two parties are engaging in a course of action which denies information to their competitor, why is that not a conspiracy?

Senator CAROL BROWN—You asked that question and he answered that question.

CHAIR—I understand that and Senator Trood understands that as well, and he has made his statement for the record. You are asking officers to give an opinion, Senator, and you well know that it is not appropriate. You have put your position on record and the officers have said that with all the negotiations they had it is not their right to give an opinion.

Senator TROOD—Can we clarify this, Mr Learmonth: when do you understand that GMiA learned about the MOU?

Mr Stuart—There are two parts to that answer. One is that there was a certain amount of leaking into the public arena of information about discussions, which appeared in newsprint—

Senator BOYCE—But presumably, not from the department.

Mr Stuart—Not from the department, no. Formally, I contacted GMiA the day after the MOU was agreed and—

Senator BOYCE—What day was that?

Mr Stuart—It was two days before the budget—that is my memory—to advise them that we had reached an MOU and I offered to provide a confidential briefing on budget eve to the GMiA about—

Senator FIERRAVANTI-WELLS—It was a bit late—it was all over red rover, Mr Stuart.

Mr Stuart—I am not trying to portray that as consultation, Senator. I am stating that that was advice to GMiA.

Senator FIERRAVANTI-WELLS—Mr Learmonth, can I just take you back to a couple of points that you made. You started off this process as a discussion, as I understand, purely on PBS reform.

Mr Learmonth—On sustainability of the PBS, broadly.

Senator FIERRAVANTI-WELLS—Did you go out to people including GMiA and Medicines Australia and other stakeholders in the industry and invite them to come to you? How did you do this process? What process did you undertake?

Mr Learmonth—It was a process of the informal discussion with those stakeholders. It is not as if we do not have regular contact with these stakeholders. All of the stakeholders in question we do business with every week. We are regularly talking with them about policy, administration and management of the PBS. Within that context we started the discussion with them on the sustainability of the PBS.

Senator FIERRAVANTI-WELLS—So you have had discussion. The wholesalers came this morning and gave us some evidence, the consumers have given us evidence as well, and I am sure that in the other submissions there are other people who were not consulted. But at what point did you or the department or the government decide that you were going to have an MOU? What was the date of that?

Mr Learmonth—I am not sure that we could narrow it down to a date. It was relatively late in the piece. As I said, it was not the intention upfront. Indeed, it was a suggestion from Medicines Australia and not us. My

guess would be that it was April this year but I do not think we could even nail down a day. It was not an a priori objective.

Senator FIERRAVANTI-WELLS—So let me get this straight. Dr Shaw could not remember, if I recall his evidence this morning, as to whether the approach was made by Medicines Australia or from the department to enter into an agreement. You are saying that it was a proposition put up to government by Medicines Australia. Is that your clear evidence?

Mr Learmonth—There are two things, Senator. I am saying that the notion of an agreement—MOU, call it what you will—came late in the piece. It followed some discussion about what might be an accommodation between government and Medicines Australia. As that was, I think, nearing conclusion my clear recollection is that the notion of an agreement—indeed, I think they used the word 'contract'—came from Medicines Australia to embody what we had been talking about and that resulted in the notion of an MOU.

Senator FIERRAVANTI-WELLS—How late is 'late'—a week before the budget, two weeks before?

Mr Learmonth—I would have to take that notice—I cannot recall. My recollection is that it was somewhere around April, perhaps.

Senator FIERRAVANTI-WELLS—The point that I am making is this: at that particular point was it not unreasonable for you to think that this was going to have a major impact on this industry and that perhaps we ought to consult a bit more broadly than just entering into an agreement with one entity?

Mr Learmonth—There are, if you like, two aspects to the MoU, one of which is a series of strengthening and deepening of the existing price disclosure mechanisms. We understood very clearly what the view of the rest of the industry was; they had put it to us clearly a number of times. The rest of the MoU concerned a range of things around process improvement to the PBS and timeliness of listing of medicines, which all stakeholders, both manufacturers and consumers, would benefit from.

Senator FIERRAVANTI-WELLS—But if you are having a discussion in the context of reform, a position of the party may be A, B, C and D. But if that discussion is held in the context of a formal agreement to be signed that has a life of three or four years then surely is it not reasonable to think that potentially if an entity, whether it be GMIA, Consumers Forum or any other stakeholder, perhaps their position may have been different knowing that it was going to be an agreement in place for three or four years that is going to materially affect their interests, firstly. Secondly, surely it would have been reasonable, because you are affecting the financial and potentially legal interests of these entities, that you would have consulted with them because of these new parameters that you were negotiating?

Mr Learmonth—I cannot speculate on how anyone might have thought differently if they knew there was an agreement. All I can say is that to the extent the agreement has actually effect, in other words to the extent that it has content and reflects what you are going to do, again we were extremely clear about what all the players thought about that in so far as it affected them financially.

Senator FIERRAVANTI-WELLS—That is a bit presumptuous of you. If I am negotiating on behalf of a client, the position of one of my clients when I was practising law if I knew that they were thinking in terms of generalities, but when it comes to perhaps an actual contract that is going to affect their livelihood over the next three years perhaps they may have made some concessions, but you did not even bother to ask them, you simply went ahead, signed your agreement with Medicines Australia and did not bother to consult with whether it was GMIA or the consumers or anybody else whose material interests were affected by this agreement.

Mr Learmonth—Again, we were very clear on what those organisations thought. It is not a question of whether or not they might have been prepared to accommodate a bit more of the same, a bit more price disclosure; they were clear that they did not want the existing scheme of price disclosure to apply.

Senator BOYCE—Did you go back—

Senator FIERRAVANTI-WELLS—That is right. Did anyone—

Senator BOYCE—and ask—

CHAIR—Senators, there will be one person speaking at a time. I do not care who it is but just one of you will speak at a time.

Senator BOYCE—We are happy to talk together.

CHAIR—But not over the top of each other. It is impossible for Hansard to handle. Senator Boyce, you have the call.

Senator BOYCE—Did someone from the department go back to GMIA and say, 'Your major competitor are considering discounts and are negotiating on price disclosure. What do you say now?'

Mr Learmonth—No, Senator.

Senator BOYCE—Why didn't you do that?

Mr Learmonth—I can only say again that we understood very clearly what their views on price disclosure were. They did not want it; they did not want the existing scheme.

Senator FIERRAVANTI-WELLS—Given the evidence that we have now heard today and in other submissions as well, what about the prospect of consulting now in relation to this agreement? We have heard that there are ramifications for various entities in relation to this agreement. Why shouldn't we perhaps revisit this agreement?

Mr Learmonth—The agreement has been signed—

Senator FIERRAVANTI-WELLS—Let me rephrase that: why shouldn't we now have a process where potentially that agreement now may be put on the table and revisited taking into account the views of everybody?

Mr Learmonth—I guess that is what this is. The expression of the agreement is in the bill before the parliament and it will be up to the parliament to take into account those views in dealing with it.

Senator FIERRAVANTI-WELLS—Can I ask you what then could be a feasible process that could be undertaken at this point to revisit this agreement, given the evidence that has been given to this committee and has been produced in the various submissions?

Mr Learmonth—It is not clear to me that there is a need to revisit the agreement. We are clear about the views of the various players on the fundamentals of the policy. In relation to the administration of the policy, there is significant and ongoing consultation as to how the policy would work in practice through the price disclosure working group, on which GMiA is represented along with AusBiotech, NPSA and Medicines Australia. So there remains material and ongoing genuine consultation, from our perspective, on how to administer this proposition in a way that is as simple as possible.

Senator FIERRAVANTI-WELLS—So in other words you are not open to any variation of the terms of that agreement even if there were a proposition put by other affected parties?

Mr Learmonth—The agreement reflects what government has decided is policy. It is a matter for government to consider any variations to the policy as it is espoused and reflected in the legislation that is brought before the house.

Senator FIERRAVANTI-WELLS—Can I ask you then about the logistics of it. What practical processes could be now undertaken to vary the terms of that agreement? It could be as in the past. When we introduced the reforms in the first place there was consultation right across the spectrum that resulted in a series of reforms. Why could you not have undertaken a similar process whereby everybody was on the same page?

Mr Learmonth—I am not sure I can add any more to what I have said by way of consultation. We are clear about the views, we are consulting on the implementation and the bill is before the parliament.

Senator TROOD—When you say you are consulting on the implementation, Mr Learmonth, you are saying you are doing this in the working groups—is that right?

Mr Learmonth—That is what I have said.

Senator TROOD—And have GMiA been consulted?

Mr Learmonth—Yes.

Senator TROOD—And have GMiA been actively participating in the working groups?

Mr Learmonth—My colleagues would have more detail. The answer is, I think, yes. They have been briefed, they have been engaged and they have attended the meetings and the conversations. They have provided some views. I am not sure that they continue to provide views, or not.

Senator TROOD—Dr Shaw is behind you. He is obviously shaking his head.

Senator BOYCE—Mr Learmonth, there is a fair bit going on behind you. There is a fair bit of headshaking going on behind you, Mr Learmonth.

Mr Learmonth—GMiA have been invited to this working group. They have attended this working group. They have expressed some views. More recently they have decided that it may appear as though they were blessing the ongoing work, and so they have chosen to keep their peace. Nevertheless—

Senator BOYCE—Sorry, what do you mean by 'keep their peace'?

Mr Learmonth—To observe rather than to participate fully. They were active participants at the beginning. Nevertheless staff of mine visited both Alphapharm and Sigma, as part of visits to companies, and engaged with—

Senator BOYCE—For what purpose?

Mr Learmonth—To understand how price disclosure functions at the company level and to work towards simpler and less costly approaches to obtaining data under price disclosure, which is actually, with those processes—

Senator FIERRAVANTI-WELLS—Wouldn't it have been smart to do that before you entered into an agreement that was going to affect their interests?

Mr Learmonth—This is a how, not a whether. The agreement is merely where and what will be done. This is consultation on the how and there is a lot of effort going into determining how we are going to do this in a way that is as easy as possible.

Senator FIERRAVANTI-WELLS—Mr Learmonth, you have entered into an agreement that does not affect just the interests of the party that you are negotiating with. It affects the interests of a range of other entities outside that agreement. Surely it would have been at least reasonable to contemplate consulting with them before you entered into an agreement that is going to have an effect on their day-to-day operations. We have heard from various parties this morning. There are others out there. Is this another case like you had with the Better Health Initiative, where you went out there, made a budget decision, because you needed more money, and then forgot about the consequences and now you are picking up the pieces in all sorts of different areas in the department because you have to find money quickly? Be upfront about it.

CHAIR—Senator, I do not think it is appropriate for the officer. Again you have moved into a wider range of questions. You asked about consultation and you have put a position in front of them—

Senator FIERRAVANTI-WELLS—Senator, we are talking about—

CHAIR—Senator, if you are challenging my ruling you can. And—

Senator FIERRAVANTI-WELLS—I am not challenging your ruling. All I am saying is there is no minister present here to ask the question of.

CHAIR—Senator, it is one of the rules of these committees that you do not talk over the chair. You have actually raised a number of issues about the process. The officers have responded. You have put your issues on the record. You have talked about the timing of the actual work that has been done. It has now drifted into a wide-ranging political discussion. We should pull it back to questions that the officers can respond to. If you have questions for the minister, please provide them to me and I will give them to the minister. These are not the people that can answer them. In terms of consultation, is there anything we have not touched on yet that needs to be looked at about the process?

Senator CAROL BROWN—I wanted clarification because my understanding of the evidence that you have given is that you went into these consultations with Medicines Australia and GMiA in good faith looking for reforms to underpin the sustainability of the PBS.

Mr Learmonth—Correct, Senator. We did not go in with a particular proposition or a thought-out project or a notion of MOU, we started off with a general discussion.

Senator CAROL BROWN—And it seems to me that the only ones that came to the table were Medicines Australia.

Mr Learmonth—And the Pharmacy Guild to be fair, both in supporting this MOU and indeed in offering up a billion dollars of savings in their agreement.

Senator CAROL BROWN—The evidence you have given is that GMiA were from the very beginning not interested in price disclosure.

Mr Learmonth—Certainly their interest was in eliminating it, not in accelerating it.

Senator CAROL BROWN—Because, quite frankly, value for money for Australian taxpayers and making sure that Australian consumers receive the medicines they need are the priorities for me. We heard in evidence given today about discounting. I think it was Dr Shaw who gave us a picture of how discounting could be up to 70 per cent, the product might be 100 per cent and so they are selling the product to the pharmacy for 30 per cent and the Australian taxpayer and the Australian government are paying $100. That is very concerning. Do you have any information as to the extent to which that goes on?

Mr Learmonth—We do. We have a variety of sources. Obviously, we have some anecdotal evidence about the degree of disclosure. My colleagues can add more but we have two other sources. Firstly, we know what commodity prices are in other jurisdictions. We know what other people are paying. Secondly, we do have some experience with price disclosure—it does exist. We are seeing discounts in medicines that are already subject to disclosure ranging from quite low to up to 70 per cent in some cases. So we have got good evidence of a range of discounts and certainly good indication from offshore pricing about what is likely.

Ms Platona—There are 15 drugs now that have had a price reduction as a result of price disclosure. Mr Learmonth correctly said that the range is between 12 per cent to 72 per cent of price reduction. Out of those 15 drugs, six of them have actually incurred a second price reduction. That demonstrates that, for these products that have a price reduction to start with, there was further discounting that was captured subsequently and there were some more price reductions that we have achieved in these six drugs.

Mr Learmonth—I will give you an example. Sometimes the saving does not accrue to government; it actually accrues to the patient. Vancomycin, an antibiotic has been subject to price disclosure. Pre price disclosure the price was $33.30. Following price disclosure the price is $12.19. Those patients paying a general co-payment will be saving $21.11.

Senator TROOD—Senator Brown does not have a monopoly in the virtue of driving down the costs of the PBS.

Senator CAROL BROWN—I never suggested I did.

Senator TROOD—Driving down the costs of the PBS to both the taxpayer and the consumer is a virtue. I think that is a common view here. That is not under debate. The question is the means by which you achieve these objectives. Our concern in part is that you have done this in a way which excludes some very material parties to the discussion. If I may, I would like to move on.

Senator FIERRAVANTI-WELLS—I have one more question in this area. You said that you started a range of discussions as far as PBS reform was concerned with a number of people—the stakeholders. I take that to mean stakeholders right across the industry, is that correct?

Mr Learmonth—I do not know what you mean by 'right across the industry'. Principally, we had discussions with Medicines Australia, the guild and GMiA. We did, I think, have some discussions with these issues with NPSA. It depends what you mean, Senator.

Senator FIERRAVANTI-WELLS—Perhaps it would be useful to know who you started these discussions with—that would be a good start. When did you consult with the Pharmacy Guild?

Mr Learmonth—That would have started first. There is an inevitable trajectory to that, given the rolling pharmacy agreements.

Senator FIERRAVANTI-WELLS—I agree with that.

Mr Learmonth—Right at the beginning we started off with sustainability of PBS, and they are part of that, so they would have been first cab of the rank.

Senator FIERRAVANTI-WELLS—Who directed the guild? Were the negotiations with the guild with their chairman?

Mr Learmonth—It was principally with Mr Sclavos, the chair, and Ms Riley, one of their counsellors, but their board was involved.

Senator FIERRAVANTI-WELLS—I appreciate that. They got compensation in the budget, did they not?

Mr Learmonth—I would not call it compensation, no.

Senator TROOD—Transition arrangements.

Mr Learmonth—There was some adjustment—

Senator FIERRAVANTI-WELLS—It was $277 million, I understand. It is quite a nice little sum.

Mr Learmonth—There was some foldback of savings into pharmacy programs for consumers, yes.

Senator FIERRAVANTI-WELLS—That is a nice little compensation, really, when you look at it, for traders.

Mr Learmonth—It was part of the overall agreement.

Senator BOYCE—What was it?

Senator FIERRAVANTI-WELLS—What was it for?

Mr Learmonth—It was to fund a range of programs.

Mr Bessell—The $277 million was folded back into the agreement, as you say. It was focused on patient-focused programs. It was not part of remuneration. It was in recognition that the further reforms to the PBS would have an impact on pharmacy. However, the pharmacy had already offered $1 billion in savings through the agreement, and the further savings that would have been generated were folded back in recognition of the generous save that the guild had already provided.

Senator FIERRAVANTI-WELLS—So you have got one player over here that you are having discussions with. They are going to be affected, so they get compensation. You have got Medicines Australia that you enter into an agreement with—

Mr Learmonth—Senator, I am sorry; I have to take issue with 'compensation'. It is not compensation.

Senator FIERRAVANTI-WELLS—I withdraw 'compensation' and say 'an amount paid to them' in lieu—

Mr Learmonth—Well, look—

Senator FIERRAVANTI-WELLS—Mr Bessell has just said—

Mr Learmonth—It was not in lieu either. We are talking about a saving in the order of $1.9 billion. We are talking about it as part of an agreement with the guild, reaching agreement on an additional amount that would be paid into programs for the benefit of consumers. I would not at all characterise it as compensation.

Senator FIERRAVANTI-WELLS—That is fine, Mr Learmonth. Perhaps you would like to take on notice precisely a breakdown of that $277 million and what it was for.

Mr Learmonth—I would be very happy to.

Senator FIERRAVANTI-WELLS—In other words, you have two agreements, two key players, both of whom get benefits out. But not only were the other key stakeholders not consulted; they obviously did not have the opportunity to put their bid forward in terms of the potential financial effects that they could have and whether, as a consequence of those effects, they themselves could then be part of that agreement. We still come back to that and we still have issues out there. Anyway, Senator Trood has some questions so I will leave it there.

Senator TROOD—The MOU and the legislation is based on the premise that we need to contain the costs of the PBS—is that right?

Mr Learmonth—Sustainability of the PBS, yes.

Senator TROOD—Okay. do you accept the proposition that is contained in GMiA's submission that the costs of the PBS are increasing more quickly in the F1 formulary than in the F2?

Mr Stuart—Yes, we believe that to be true.

Senator TROOD—What do these reforms do to try to drive the costs down in the F1 formulary?

Mr Learmonth—There are a couple of things about F1. F1 already has a very, very effective pricing mechanism, which is essentially the independent expert Pharmaceutical Benefits Advisory Committee which applies a comparative cost-effectiveness test to any medicine seeking listing on the PBAC, including on F1. There are a range of pricing policies that continue to operate under the MOU—reference pricing, existing therapeutic reps and so on. None of those pricing policies are in abeyance. They continue to operate.

I think the evidence that you heard from others this morning was that Australia does pretty well in terms of getting good prices for medicines on F1, by a world standard. That is certainly our judgment as well in looking at those. Indeed, what can often be the case for new medicines coming into F1 is that the final sticking point with the company, having been through PBAC, having had a risk share negotiated with the PBPA, is the notion that the world is going to see what they are giving us the medicine for by way of price. We do pretty well out

of F1. This is where all the new medicines come in for patient benefit. It is the pipeline for new, innovative drugs, which obviously are important to us.

Senator TROOD—Would you agree that there is no room for complacency in relation to F1, and that the mechanisms which are in place which help drive down the costs for F1—which is the area where the costs are growing more quickly than anywhere else—need to be implemented strongly and that we need to strongly monitor those costs?

Mr Learmonth—The existing pricing regime for F1 remains untouched by this MOU.

Senator TROOD—That is not quite true, is it?

Mr Learmonth—It is, I am afraid.

Senator TROOD—If I misunderstand it, then please correct me, but in relation to therapeutic groups, for example, your submission to us tells us, on page 16, that therapeutic groups have been 'a price saving measure in which a number of similar acting drugs are priced at the cost of the cheapest one in that group'. Is that right?

Mr Learmonth—Yes. If I go on perhaps to anticipate your question, the existing pricing policy and the existing therapeutic groups remain and if there are new medicines that come along which would be appropriate, on the advice of the PBAC, to include in an existing therapeutic group, they will be so included. The MOU does not preclude that. The MOU precludes the formation of new—that is, non-existing—therapeutic groups for the next 3½ years or so. But, as I say, the existing pricing policy mechanisms of F1 remain untouched.

Senator TROOD—I acknowledge the point that you are making that there is a provision in the MOU which allows therapeutic groups to be continued in a very specific set of circumstances, but it precludes the creation of further therapeutic groups, doesn't it?

Mr Learmonth—Only for the duration of the MOU.

Senator TROOD—But that is four years. Therapeutic groups have been part of the system, as I understand it—on your evidence and from your submission—since 1997. Is that right?

Mr Learmonth—Yes.

Senator TROOD—Do you believe that they have been an effective means of containing costs?

Mr Learmonth—Yes.

Senator TROOD—If they were to continue as part of the mechanism for containing costs over the next four years, might they not save further costs to the PBS?

Mr Learmonth—There are several things. First of all, as I said, the existing therapeutic groups continue to apply and they will be added to if circumstances suggest that is appropriate, if new medicines come in. New therapeutic groups cannot be formed for the duration of the MOU. There is nothing to preclude new therapeutic groups being formed after the MOU. The agreement with Medicines Australia in relation to the MOU was taken in the broad context of what was a balance of benefit. The government took the view that, on balance, the MOU was in the public interest in all of its content, and this was part and parcel of it.

Senator TROOD—But Medicines Australia did not want any further therapeutic groups created, did they?

Mr Learmonth—That is the reason why the MOU reflects that, but equally the MOU does not preclude the addition of new medicines to existing therapeutic groups if that is appropriate, or the creation of new therapeutic groups after the expiration.

Senator TROOD—But there is a four-year period during which you cannot create any further therapeutic groups, and you acknowledge that these have been an effective means of saving money in the PBS.

Mr Learmonth—Correct.

Senator TROOD—So you are setting aside for a four-year period what could be tens of millions or hundreds of millions of dollars. It might even be more—I do not know—but it is a significant amount of money which will be a cost to the PBS and it is being forgone because you have decided as a matter of policy that there will be no further new therapeutic groups created.

Mr Learmonth—I think the judgment was overall that the propositions contained within the MOU deliver clear net public benefit in terms of a $1.9 billion saving and timely access to new medicines. The government's view was that on balance that was to the public benefit.

Senator TROOD—Why is the public benefit not served by allowing the potential to create further therapeutic groups which might save the PBS further money?

Mr Learmonth—At the end of the day, there are any number of things that you might or might not do to improve sustainability. You could tender; you could do all sorts of things. The MOU reflects the accommodation that was reached.

Senator TROOD—We are not talking about tendering. Tendering has not been part of the system. But, for over a decade, therapeutic groups have been part of the system. You acknowledged their importance in driving down costs and you in fact are precluding them for four years as a means of driving further cost savings in the PBS. Why is that good policy?

Mr Learmonth—There is nothing more I can add to this. I have explained to you how it works. I have explained to you what is precluded and what is not. I have explained to you that the MOU, on balance, represents a public benefit in the judgment of the government.

Senator TROOD—I understand what you are telling us. What I do not understand is the policy rationale behind it, because you have failed to explain it.

CHAIR—Senator, Senator Siewert has a question on this issue and then we are going to have to move on.

Senator SIEWERT—In fact I have one question on this issue and another question on another issue. Can you remind me of the dates of the last therapeutic groups?

Mr Learmonth—Are they the ones that were disallowed recently?

Senator SIEWERT—Maybe you could take it on notice, but I would like the history of when they were—just to remind us of when you—

Senator FIERRAVANTI-WELLS—The ones that were the subject of the last one.

Mr Learmonth—Would you like the last one or more of the history?

Senator SIEWERT—The last ones and then more of the history.

Mr Learmonth—I think we are supplying that on notice from the last inquiry. We can certainly give that to you.

Senator SIEWERT—The other question is one that came up this morning. This morning, the GMIA raised the issue of whether this process is legal—whether it contradicts the Trade Practices Act. Have you had advice on whether that is—

Mr Learmonth—I do not know if we have had specific advice, but the process of legislation is that policy instructions are provided to the Office of Legislative Drafting and Publishing. As I understand it they, as a matter of course, consider the constitutionality, legality, appropriateness and a whole bunch of other dimensions of any proposed legislation. We have had no feedback of concern from them on the topic.

Senator SIEWERT—I take their point in that you have signed an MOU with one group that affects another group. So I would be interested—

Mr Learmonth—But this is about policy formulation at the end of the day, not whether the legislation is constitutional or legal.

Senator SIEWERT—I understand what you are saying, that it is policy, but that policy could be seen to advantage—and that is the argument being put to us—one group in this sector over another. That is the argument that was put to us this morning, if I understood it correctly.

Mr Learmonth—I guess our assessment is that one group, Medicines Australia, represents the lion's share of this and that, in any event, it is within the government's legal and policy prerogatives to bring forward this legislation, however that policy may have been derived.

Mr Stuart—And we do not accept the premise that one group is disadvantaged and another advantaged. Price disclosure is taking savings out of all off-patent medicines.

Senator SIEWERT—I appreciate that you do not think that one group is advantaged and another advantaged. Obviously, it has been put to us that there is a group that do think so. Please take on notice any checks that were done in terms of—

Mr Learmonth—I can tell you now that nothing has been raised with us from the lawyers that are drafters on the topic.

CHAIR—There will be a number of questions on notice, Mr Learmonth, from various senators, in particular, some of the things we noted this morning from evidence. One question relates to the issues raised by the Pharmacy Guild about implementation dates and the arguments that they said they have raised with you about the dates—

Mr Learmonth—We believe there was some misunderstanding there on the part of the guild and it is not what they had imagined, so we will be very comfortable responding to that on notice.

CHAIR—Can we have that clarified—a response on that?

Mr Learmonth—Yes, absolutely.

CHAIR—We will not be able to hear from the Pharmacy Guild to see if they agree that there has been a misunderstanding, but the Pharmacy Guild, in their evidence this morning, spent considerable time talking about the implementation dates and why they thought those dates should be deferred. Do you have a response you can share with us now on that?

Ms Platona—In their supplementary submission, the guild says:

It appears that the new Bill was written with the expectation that it would be passed at the September sittings—

and they referred to the date of 11 October as of significance to price disclosure. That date of 11 October is completely unrelated to price disclosure. It is simply that drugs not on Formulary 2 on that date will be subject to statutory price reductions from 1 February. It is completely unrelated to price disclosure. Price disclosure—

Mr Stuart—There are two relevant dates for price disclosure.

Mr Learmonth—In a nutshell, senators, my understanding is that the guild were under the impression that disclosure would start much earlier than it actually would.

CHAIR—The argument they put in evidence was that, over the busiest time for their dispensing period, they would be required to change their methodologies.

Mr Learmonth—No. The data collection system is delayed.

CHAIR—We will ask the guild. I am sure there is someone from the guild watching. If not, we will be contacting them this afternoon to clarify.

Senator FIERRAVANTI-WELLS—Senator Moore, given that this committee has been considering the position of those three therapeutic groups, where does that now leave us? I think it is a legitimate question.

CHAIR—Untouched, Senator, in terms of that process. I have asked that previously.

Mr Learmonth—They are not caught within the MOU, no.

Senator FIERRAVANTI-WELLS—They are not caught within that?

Mr Learmonth—Explicitly.

CHAIR—That is clarified in the process. We had that answer to our previous inquiry to have that qualified, because, if you remember, the MOU was signed in the middle of our consideration of that process. We will contact the guild.

The other thing was to do with the distributors and the wholesalers, who talked about the impact on their business and the fact that they needed some compensation—using the term directly from them. Senator Fierravanti-Wells was moving around that question but did not identify them specifically around the wholesalers, so, if we can get something on notice about the relationship with the wholesalers and the arguments they raised, it would be very useful.

Security of supply was raised by a number of witnesses in terms of fears that somehow the implementation of this process could cause issues around security of supply. We will provide these questions in writing to the department. Senators, are there any issues that you need to follow up on that you wish to put on notice now, before they go?

Senator FIERRAVANTI-WELLS—Mr Learmonth, those three therapeutic groups that were the subject of the inquiry—you were very keen to ensure that they stayed on foot, and Medicines Australia and their various components gave evidence that they did not want them to proceed. Will that process continue and those three groups—

Mr Learmonth—That will be a matter for government, Senator, but they are excluded from the MOU.

Senator FIERRAVANTI-WELLS—We were looking at them because they were disallowable instruments—

Mr Learmonth—Yes.

Senator FIERRAVANTI-WELLS—so now it is a matter as to whether the government re-presents them?

Mr Learmonth—That is correct.

Senator FIERRAVANTI-WELLS—So it may be that, as a consequence of this agreement that you have entered into, we will not see those three therapeutic groups—

Mr Learmonth—No, that is not right. They are excluded from the MOU.

Senator FIERRAVANTI-WELLS—But it is still open to you now to make that decision in the spirit of the MOU—to not present these therapeutic groups again.

Mr Learmonth—No, those therapeutic groups were explicitly the topic of discussion and they are explicitly carved out.

Senator FIERRAVANTI-WELLS—So you will be pursuing those three?

Mr Learmonth—Whether they are pursued will be a decision for government.

Senator FIERRAVANTI-WELLS—Right.

Senator TROOD—Chair, I do have a question.

CHAIR—And you will be putting it on notice, Senator.

Senator TROOD—I am just giving notice of the question, which relates to the amount of money that has already been spent on the education program in relation to generics. There was a fund set aside of $10 million or something?

Mr Learmonth—Do you mean the prospective one, not the old one?

Senator TROOD—Yes—

Mr Learmonth—The new one.

Senator TROOD—Yes. I would like to know how much has been spent from the old one and whether it has all been expended.

Ms Platona—It was $5 million for the period.

Mr Learmonth—We will provide it on notice. We will give you both, Senator.

Senator TROOD—Thank you.

CHAIR—The last one we made notes of here for specific questions to the department was around the wholesalers again. There was confusion about the interaction that they had had with the department and the minister in terms of information, so you may want to review the *Hansard* and see the actual exchange. Exactly when was information exchanged and by whom?

Mr Learmonth—Yes.

CHAIR—Thank you very much to the officers of the department, as always. You have those notes. We as a committee will try to get the specific questions to you this afternoon by five o'clock. We need the answers by the end of the week.

Mr Learmonth—Thank you, Senator. We did have Senator Fierravanti-Wells's questions on the break-up of the $277 million—the guild—and also the market share volume and price.

Senator FIERRAVANTI-WELLS—And the table.

Mr Learmonth—The table, yes.

CHAIR—Thank you very much. That ends today's hearing on the National Health Amendment (Pharmaceutical Benefits Scheme) Bill 2010.

Committee adjourned at 2.29 pm