



COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

STANDING COMMITTEE ON COMMUNITY AFFAIRS

**Reference: National Health (Pharmaceutical Benefits-Charges) Regulations 2008
[Draft]**

THURSDAY, 25 SEPTEMBER 2008

CANBERRA

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**SENATE STANDING COMMITTEE ON
COMMUNITY AFFAIRS**

Thursday, 25 September 2008

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

Participating members: Senators Abetz, Arbib, Barnett, Bernardi, Birmingham, Mark Bishop, Boswell, Brandis, Bob Brown, Bushby, Cameron, Cash, Colbeck, Jacinta Collins, Coonan, Cormann, Crossin, Eggleston, Ellison, Farrell, Feeney, Fielding, Fierravanti-Wells, Fifield, Fisher, Forshaw, Hanson-Young, Hefernan, Hurley, Hutchins, Johnston, Joyce, Kroger, Ludlam, Ian Macdonald, McEwen, McGauran, McLucas, 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 Adams, Boyce, Colbeck, Furner, Humphries, Moore and Ryan

Terms of reference for the inquiry:

To inquire into and report on:

National Health (Pharmaceutical Benefits—Charges) Regulations 2008 [Draft]

WITNESSES

BUSCH, Mr Roger, Director, Policy Implementation and Budget Section, Pharmaceutical Benefits Division, Department of Health and Ageing 6

CAMPION, Ms Sue, Acting First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing 6

CARNEY, Professor Shane Lachlan, Chair, Therapeutics Advisory Committee, Royal Australasian College of Physicians 1

LEARMONTH, Mr David, Deputy Secretary, Department of Health and Ageing 6

MACDONNELL, Mrs Diana, Acting Assistant Secretary, Pharmaceutical Evaluation Branch, Department of Health and Ageing 6

Committee met at 3.09 pm**CARNEY, Professor Shane Lachlan, Chair, Therapeutics Advisory Committee, Royal Australasian College of Physicians**

Evidence was taken via teleconference—

CHAIR (Senator Moore)—Good afternoon. The committee is continuing its inquiry into the National Health (Pharmaceutical Benefits—Charges) Regulations 2008 consultation draft. I remind people that the Senate is sitting and senators will be moving in and out throughout the afternoon, so it is by no means a reflection on their interest in your evidence. Professor Carney, thank you for your patience. I know you have information on parliamentary privilege and the protection of witnesses in giving evidence. I invite you to make a short opening statement and, at the end, we will go to questions. At the moment we have here Senator Colbeck, from Tasmania, and me. Other senators will be joining us, but the questions will be started by Senator Colbeck.

Prof. Carney—I would first like to thank you for allowing the college and myself to comment on this PBAC funding cost recovery model again. The last time, when I was in Canberra and commented on this, I mainly tried to raise various issues and did not really come up with a decision as to what the college and its affiliated speciality societies felt about the proposal. Since then, I have had a chance to talk not only within the college, including my therapeutics committee, which met two days ago, but also to a number of affiliated specialty societies—not all, but a fair number including oncology, rheumatology, paediatrics, geriatrics, nephrology, cardiology and a couple of others. We have a large number of the various specialty groups, specialist physicians around the country who are associated with the college. Following those discussions, I can say with some confidence that there is no support for the proposal before the Senate at the moment.

I want to very briefly talk about the reasons why we feel this way. The first thing to say is that the PBAC has become a very important part of the National Medicines Policy, and some of you may be aware that there is such a policy that has been approved by government quite a while ago. In particular, we feel it facilitates prompt access to cost-effective new medicines. Not only is it highly regarded by prescribers and industry, but also consumers are becoming well aware of the particular benefits of this very flexible, very novel committee. Furthermore, it now has very strong credibility overseas, which I think must be considered. Not only has it allowed the use of medicines in a timely fashion, but it has also started to develop links with prescriber and consumer organisations, not just industry. I would like to talk briefly about that in a moment. Consequently I think it really is serving patients, and therefore the government, extremely well and the concern is that anything that happens may make the situation not necessarily better but possibly worse.

From a specific point of view, you will have had industry tell you about the issue of fees and that adding an additional fee—apart from the money it costs them to prepare a submission—may be a disincentive where they feel that the medication may have a limited financial return. I think that is common sense. Certainly the fee waiver has been proposed, but, as they say, and I think it would be reasonable to agree, they cannot be necessarily sure that they will get a fee waiver at the time and it may, again, not be so much of an incentive. Nevertheless, I feel if this program is going to occur and fee waivers considered, this needs to be enlarged—particularly to include

paediatrics. As I mentioned last time I spoke to you, in paediatrics there is such a large number of medications that are used off-label. In fact, I was asked last time how many. The current estimate is that roughly three-quarters of all prescription medicines written in paediatrics—and the younger the child, the more likely it is—are off-label, where there are no clear indications. So there is a big issue, and if there is any disincentive towards research and allowing these to be used under certain criteria—in other words, if industry feels they will not make any money out of it then why should they bother—then that would be of grave concern.

And there is another group; it is not just paediatrics, but geriatrics. Unfortunately, very little research is done in the extreme ages. Most of the work is done in the middle. These groups are often disadvantaged and industry will often feel there is not the work there to really prove the point or, if they do, they are already being used, so why should they bother making any approach to PBAC or even TGA for that matter, and therefore they do not.

To try to explain the real problems about fees, I can maybe go back to the issue of the TGA, which is fee recovery. There are a number of instances in my own personal approach, where the issue of fees has stopped situations occurring. For example, I mentioned last time that one of the generic companies was told that the WHO classification for one of their antibiotics had change and, on approaching the TGA, which is cost recovery, they were told, ‘That’s fine, give us \$85,000 and we’ll talk.’ There has been some negotiation since, but you can understand when, in this situation, there was going to be no extra financial incentives to the company, they were not making any more money, then it is a disincentive. In my own society—that is, kidney specialists, nephrology—a number of years ago many people were using a particular vitamin D off-label. In some ways many people were doing it in contravention of the law because they were using it where the indications were not there and it is an authority and quite an expensive medication. On going to industry and saying, ‘Look, we need to rectify this,’ they said: ‘Look, we agree, but it’s already being used, we’re not going to make any money out of it. It will cost us \$200,000 or \$300,000, apart from an application’—this is of course to the TGA, not to PBAC initially—‘and therefore we’re not prepared to do it.’ I think there is a real worry that the fee will be a disincentive.

There is another area that concerns us, and you are well aware of this and industry will argue this very accurately. It was mentioned before that at the moment PBAC is trying to develop close links with consumer groups and also specialty societies. I will be meeting with Lloyd Sanson next month to try to better integrate the various specialty societies—such as cardiology, respiratory, and so forth—so that when drugs are being considered by PBAC, that these groups get more of a buy in, get more involved in the process so that the process can be improved. If any stakeholder groups are held or these groups want to be more involved, my concern is, if it is cost recovery and full cost recovery, they may say to some of the societies and also some consumer groups, ‘Okay, fine, come and talk to us, but we’ll need some money up front.’ We go to industry, they probably will not be interested and, therefore, there is a real concern to us that a process is developing, which is why it is very important to make sure that everybody gets a buy in on new medications or changes in older medications. But cost recovery may be a real problem. So it is not just the issue of industry and whether it is economically worth their while and they might decide not to do certain things, but also lots of other things are happening with PBAC because of this. I think Lloyd Sanson is an extremely good chair. It is working so well. My concerns are that the moment cost recovery comes in there, whether it is partial or complete, it may foul up a lot of good things which are happening.

In essence, we are really saying the system is working extremely well. We are very, very concerned that what is proposed will not help long term. Prescribers particularly are the consumers, and their patients. That is basically my statement. Thank you.

Senator COLBECK—Thank you very much, Professor, for your opening statement. It is quite definitive. I wanted to ask you some questions initially about your engagement with the department since our last hearings and the release of our report. My first question was, effectively, has the release of the regulations negated any of the concerns you expressed at the initial hearings, but I think it is fairly clear that has not occurred.

Prof. Carney—No. I am well aware of the intention of the government. I do not think we see government as trying to do bad things. We just feel that maybe government does not understand some of the ramifications of what has been going on and what is developing.

Senator COLBECK—You mentioned the working groups, and that was discussed earlier in the week with Palliative Care Australia. I think it is agreed the introduction of those working groups has been a very positive initiative to start working towards providing indications for the various different groups, and that is to be applauded by us all. But just going back to your opening statement, you expressed fairly significant concerns about the relationships or the impact on the consumer groups. Is that from a perspective of those that might be looking to push for an indication themselves rather than necessarily via one of the pharmaceutical companies?

Prof. Carney—Yes, that is right. In some ways the big problem is really TGA, not so much PBAC. Because, if you are going to do indication it has to go to TGA and they have the Australian Drug Evaluation Committee. That is the group that actually has to look at a new indication. Although occasionally PBAC, because of its flexibility, sometimes can include an indication that TGA may not have approved. I understand that sometimes this has led to a little bit of irritation. But usually commonsense prevails in the situation. TGA is really, I think, very much hamstrung by this cost recovery. There are a large number of medications used in Australia where the indications and the product information that patients get and doctors see are being used more and more—we call it leakage—where it is off-label. In other words there is not an indication that it is being used.

You can go to industry and they say, ‘It is already being used. Why should we spend a couple of hundred thousand dollars getting a proposal ready? Why go to TGA first and then later on to PBAC with those costs?’ It is already being used. Patients are not being disadvantaged. Yes, the waters are muddy. A patient reads the information from the doctor and says, ‘I shouldn’t be using it in this condition.’ Yet you say, ‘Yes, you should.’ They are problems which need to be addressed.

We are also meeting with TGA again to look at ways of trying to have some sort of fee waivers in some areas, particularly if we get some of the speciality societies. You mentioned the palliative care groups. There are also the rheumatology and oncology groups that have already written their own indications for a lot of these new medications. They do not fit in with the TGA or any of those. But they have already decided to do their own thing because they cannot just sit around and have patients and doctors being confused by it. It is a really difficult area but does not just involve PBAC. It really does involve TGA, and I realise that is not the focus of this hearing. Maybe I am just muddying the waters as well.

Senator COLBECK—I understand what you are saying but given that a lot of the precedents and process that is proposed for the PBAC process is lifted from the TGA process that would I presume reinforce your concerns?

Prof. Carney—Yes. It would be just be PBAC running the way TGA does. That is my big concern because we are finding it extremely difficult. As I said certain groups now put it on their websites. You will find if you go to the MOG website, which is one of the groups, you will see medications. If you look at the indications approved by TGA, and you look at theirs, they are quite different. Because they have decided that for their members and their patients they will put it down as they see it. There are legal issues in this of course. I do not quite know how they are going to be resolved. It is an area of confusion but again I would not want to see PBAC end up being in a situation where they are tied by having to get the money and then having to rely on industry who are going to say, ‘What’s in it for us?’

Senator COLBECK—I just want to ask a couple of questions about the interaction that you have had with the department. You would have had access to an initial copy of the proposed regulations in draft form from the date our report was tabled. There was another one with some guidelines, I think about the twelfth, is that the right date?

Prof. Carney—Yes.

Senator COLBECK—What other interactions have you had with the department in that intervening period?

Prof. Carney—I have not had any other directions apart from talking to Rohan Hammett on the day that I was in Canberra to talk to the Senate. I spoke to Rohan and I am going to Canberra next month to talk to him and also to Lloyd Sanson about how we can work some of these through. Especially societies with the colleges are affiliated with are all terribly keen to try and get more involved with this process and try and improve the use of medications, access of medications and so forth.

Unfortunately, with the new ones, I have only looked at them very cautiously. I have actually had an extremely bad viral infection. I have been off work since about three weeks ago and I was partially back at work last week. I am only just starting to cope and, of course, no-one does my work while I am away so I have only had a very cursory look at the new ones. I have not read it in great detail, and because I was so sick I certainly have not had a chance to talk to anybody in government. I have spoken to two members of PBAC about issues, however. One is a general practitioner and the other is a specialist, and they generally have real concerns.

Senator COLBECK—They are two members of the PBAC?

Prof. Carney—Yes. They are very committed to the process, of course. They are very much involved in it.

Senator COLBECK—I understand.

Prof. Carney—Yes.

CHAIR—My understanding is that, when the letter went out with the guidelines, there was an offer made in that for people to contact the department if they had any concerns or issues.

Prof. Carney—Yes.

CHAIR—From your evidence, that was there, but because you have been ill—

Prof. Carney—I really have. I have lost about six kilos in weight, and I am not an overweight person, so I was really feeling very sick and did things like come to work when I should not have: I checked my emails and just deleted everything.

CHAIR—Professor, that does not seem like you are taking your own advice!

Prof. Carney—My wife raised the point that there is a well-known saying that a doctor who uses himself for a doctor has a fool for a doctor. I suspect there is some truth in that. But I am now much better, and we had a meeting of our therapeutics committee last Tuesday. I am functioning fairly well now.

CHAIR—Good.

Prof. Carney—But it did make it rather difficult for me to deal with it.

CHAIR—My understanding is that you still have concerns, the ones you had when you originally gave evidence. You do not, at this stage, feel as though you have had them addressed?

Prof. Carney—No, I have not. I see the system as unchanged and with the potential for getting worse. I can understand the government's problems in the Senate at the moment; we all read about that in the paper—probably a bit too much! But I wonder whether the amount of money the government will get from it is really going to be worth it in the long term.

CHAIR—Unless you have got anything further you want to add, you have now put your statement on record.

Prof. Carney—Yes, thank you. I have nothing else to say. Thank you for hearing me.

CHAIR—Thank you. I hope you feel better soon.

[3.28 pm]

BUSCH, Mr Roger, Director, Policy Implementation and Budget Section, Pharmaceutical Benefits Division, Department of Health and Ageing

CAMPION, Ms Sue, Acting First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing

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

MACDONNELL, Mrs Diana, Acting Assistant Secretary, Pharmaceutical Evaluation Branch, Department of Health and Ageing

CHAIR—I welcome officers from the Department of Health and Ageing. Thank you for coming at a different time; we ran out of time when we had you scheduled earlier. We do appreciate your flexibility. I know you all have information on parliamentary privilege and the protection of witnesses. As you are departmental officers, I need to read into the record that you will not be asked 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. And sometimes you get questions that you just have to say no to—not in this case!

Senator COLBECK—Warnings!

CHAIR—I am just putting it on the record!

Senator COLBECK—I will try to be good.

CHAIR—The committee has copies of your submission. I invite any or all of you to make an opening statement and then we will go to questions. I know that you are aware of the evidence that was given on Monday, and it would be useful if you could address in your evidence any questions that came out of that hearing.

Mr Learmonth—I think we are happy not to make an opening statement and go to questions.

CHAIR—You want to go straight into questions? Senator Colbeck.

Senator COLBECK—I will start with the regs themselves. We have had two incarnations since our report was handed down. We appreciate the fact that the regs have been released and acknowledge that that is not necessarily something that has been a regular occurrence in the past. That is certainly appreciated by the committee and by those of us who want to be able to look at the measure. Obviously these are a draft. How close are they to being at an end point?

Mr Busch—There will be at least one more version. Mrs Macdonell signed a request to the drafters earlier this week for some more technical amendments and to respond to some comments and discussions we had with Palliative Care Australia last week.

Senator COLBECK—Can you give us an indication of what sorts of changes you might be considering, particularly given the evidence that we heard on Monday? Obviously you cannot respond to what we have heard today. Can you give us any indication of how you might be responding to the evidence that has been presented so far, both by submission and directly given to the committee?

Mrs Macdonell—We have asked for a clause to be inserted under the waiver provisions, regulation 15, to add ‘where the patient population is likely to be small and utilisation of the drug, medicinal preparation or vaccine is likely to be highly targeted’. That is one of those groups of medicines where we would waive the fee.

Senator COLBECK—So that would be where the populations are less than, say, 30,000 or 40,000—which I think was in some evidence that we heard earlier in the week.

Mrs Macdonell—It really depends whether it is a viable thing for the industry to put before us. I do not know that we would necessarily look at the population as well. It is a combination of being targeted and not viable.

Mr Learmonth—The difficulty is that there is no single factor that you can hang your hat on in terms of a threshold that will satisfy the basic test. Everything is a combination of circumstance—the treatment population, the size of the intended target, the price of the drug et cetera. There are a range of things that you have got to take into account.

Senator COLBECK—True. I was just referring to the statement tabled on Monday by Palliative Care Australia. I suppose that was talking about the total patient population in that respect, which was 40,000 or 50,000. So the indications would fall within much smaller groups within that population?

Mrs Macdonell—With a palliative care group, you would not expect to treat them for more than three or four months, for example.

Senator COLBECK—What about some suggestions that were made in respect of a reference from one of the reference groups that have been put into place, the palliative care reference group, for example, that they come with a recommendation on a drug that that drug might be favoured for a fee waiver?

Mrs Macdonell—If an organisation came to us, we would not charge them, because they are not making anything out of the drug. But the company concerned still has to consent to that, because we have to have a price. The PBAC has to look at the cost and effectiveness of the drug compared with other therapies, so there has to be a price. Those people, the individual organisations, would not know the actual price of the drug necessarily.

Senator COLBECK—So there has to be a collaboration in that circumstance between a reference group and a drug company.

Mrs Macdonell—Yes.

Senator COLBECK—So a reference group might come along and say, ‘We would like this drug considered; we’ve got a drug company prepared to put a proposal.’ There is obviously a cost to the drug company to prepare the proposal and the documentation that would go behind it. At what point in time does the drug company get the indication as to whether there is going to be a fee or not? Is the fact that the working party has said, ‘We would like this done; we’re working with the drug company,’ a criterion, or does it have to go through the decision-making process of 14 days?

Mrs Macdonell—It is certainly something that would be considered. We would hope to be able to give an indication in the presubmission meetings if a drug was going to be exempt. It is hard to give an exemption when you have not got the material in front of you. But if a company comes in with a proposal that matches what we had discussed in that meeting, then it is highly likely that they would be given an exemption. You cannot give them an exemption in writing when you have not got anything in writing.

Senator COLBECK—That comes back to the evidence that the industry gave us last Monday—that they would like to get some indication a considerable period of time before they made a submission because of the cost of actually preparing the submission. It does not appear that there is going to be any scope for that to occur in that circumstance.

Mrs Macdonell—We can give them an indication but we cannot give a guarantee.

Senator COLBECK—Which, I suppose, provides one of the differences of opinion, if you like, that there is between the two sides of this argument at the moment, where the industry is saying that they would like that certainty before expending that amount of money and the department is saying, ‘We need to have the information to make the decision.’

Mr Learmonth—They are well able to, and they do, talk about what they might provide via the submission at the presubmission meetings, and we can give them a clear indication of our disposition towards waiver at that point, as we do about other matters in relation to the submission. I think they ought to have some reasonable confidence in that. The difficulty lies in what they actually subsequently present. If what they actually subsequently present is something different to what they had anticipated at the presubmission meeting, we would have to look at it, obviously, and make the formal decision. But in the presubmission meetings they would be talking to the same people who would be taking the matters into account formally and who would be making the decision initially in relation to fee-waiver. So I think they can get a pretty good indication as early as they would wish to, in terms of a presubmission meeting, as to what the disposition will be.

Senator COLBECK—The regulations talk about progressing an application or not progressing an application without payment of fees—and I can understand the reason for doing that. It also says that an application can be withdrawn within 14 days with the return of the fees—

Mrs Macdonell—Yes.

Senator COLBECK—and that a decision on a fee waiver will be made within 14 days. Is there any mechanism for sequencing that process—

Mrs Macdonell—Yes.

Senator COLBECK—so that everything does not bump up against the end of the 14 days, if you like, so that they can effectively make decisions that are in their interests within that time frame, given that they are all based on the same time frame?

Mrs Macdonell—We would need to clarify the regulations to say that the 14 days to pay a fee or withdraw an application commences from the date of the department's notice of the decision, so they would have another 14 days after that decision about the waiver to make a decision whether they will withdraw or not. So we will clarify it.

Mr Busch—Just to clarify: we have asked the drafter to make that change.

Senator COLBECK—Okay. Turning to the consultation process: there was the first set of regulations that came out the day of our report, which, as I said, we appreciated. Then there was the second draft, which came out, I think, about 12 September, accompanied by a letter and some guidelines. Are the guidelines effectively going to be the document that will accompany the regulations, for the interpretation of the regulations—filled out, if you like, as to how the regs will operate? Or is that another document again?

Mr Busch—The explanatory statement that we have prepared, the consultation draft, explains how the regulations work and provides guidance on their effect. It is the equivalent of an explanatory statement to a piece of legislation. It is a supporting document that explains the technical terms—

Senator COLBECK—So that will be, effectively, the supporting document, when it is finalised and the regulations are finalised, that will work together so that people can pick up the regulations then go to the other document and work out an interpretation from them?

Mr Busch—It will be tabled in parliament with the regulations, yes.

Senator COLBECK—Okay. How many contacts did the department get from that mail-out?

Mrs Macdonell—We heard from Palliative Care Australia, who sought a meeting with us, and we also had contact from the Generic Medicines Industry of Australia as well.

Senator COLBECK—How does your consultation, as you have termed it in your submission, on this particular matter compare with other consultations? We heard from Medicines Australia that this was very different from their experience of other consultation processes, and they expressed some concern about it. They acknowledged that there was an invitation in the letter to contact the department, and that is evidenced by the fact that you have had two responses, but how would this compare to a normal consultation process on matters such as these? They see it as being very different, and I think you would have heard that on Monday.

Mr Learmonth—I am aware they are making that point. I think it is very hard to talk about any sort of standard consultation process. These things are always different and depend on the context, on what you are doing—whether you are introducing new legislation, making some

other policy change, consulting for the purposes of implementing a budget decision. It really depends what it is. And I think 'consultation' covers a fair gamut of levels of involvement and the nature of meetings, exchanges and periods of time. I think there has been a substantial period of consultation in relation this matter. Medicines Australia, along with others, have had numerous opportunities over time to talk about this in a variety of fora and, in relation to the latest exchange in terms of the draft coming on top of all of that previous consultation, there was that invitation there. It was in the context of relatively marginal changes to the scheme that was out in the public domain before that, and if Medicines Australia had wished anything further in that context they were quite able to pick up the phone, as they were invited to do and as they do on many issues where they wish to engage us. They most certainly pick up the phone and come and talk to us, and we are of course very open to doing that at any point.

Senator COLBECK—How can you say it was very much in the open when we did not see any draft regulations until after the committee reported? You had conversations with them, obviously, about the types of cost recovery processes. We all understand that; we heard that at the previous hearings. But how could you say that how it was going to work was well known when the largest proportion of what we talked about at the last hearings was the fact that we did not have the regulations, so we could not properly interrogate the measure?

Mr Learmonth—This is a subject that we ventilated to some extent at the last hearing, Senator, but, as I said, there was a lot of discussion in that previous consultation round, including in relation to a variety of papers about the key pieces of substance that subsequently emerged as regulations. There was a lot of time and effort put into working with Medicines Australia on this issue.

Senator COLBECK—Well, there was also a lot of concern expressed about it by a number of different submitters and those giving evidence, and I think that was the key feature of this whole process—the fact that we did not have the regs. We appreciate the fact that we do have them now, and that is why we are sitting around the table today, but I do not think we can say that the process has provided the capacity to interrogate this properly. I think that Medicines Australia probably should have picked up the phone; I am quite happy to say that I think they should have done that, but the fact is that they did not. But, given that there was so much concern expressed, why didn't the department pick up the phone, so that we did not have to have this conversation today? Just sending something out in the mail and hoping that people come back to you when you are attempting to be proactive in a consultation process, particularly given the fact that the measure has already been knocked over in the Senate—I would have thought that you would have been anxious to make sure that you had those conversations if there was a desire to get the measure through.

Mr Learmonth—As I said, we have had a lengthy consultation with Medicines Australia over time. I would not wish to put words in their mouth but I suggest that their principal concern at this point is with the existence of this as a proposal rather than with its fine detail. If they are concerned with the detail, there has been a lot of consultation and they had further opportunities to engage. They were invited to do so and did not. I suspect a large part of their concern is more with the proposition per se than the detail.

Senator COLBECK—You talked about Medicines Australia but what about the other bodies? Who did you send the document out to? Who are those that you broadly consulted with? Would you give us a list of those?

Mr Learmonth—We have a substantial list and we can table that for you. Would you like me to run through it or table it?

Senator COLBECK—I would like the opportunity to quickly look over it. Roughly how many are on the list?

Mr Learmonth—My colleague just told me there are about a dozen.

Senator COLBECK—So out of all of those you got two responses.

Mr Learmonth—Correct.

Senator COLBECK—Was it a concern to you at all that you only got two responses?

Mr Learmonth—Perhaps it was an indication of the extent to which we have had a lot of meaningful conversations with these people in the lead-up.

Senator COLBECK—How come that is not reflected in their submissions to us. If they think they are happy with it why are they not expressing that in their submissions?

Mr Learmonth—I cannot speak for them. I can tell you that they have not engaged with us and they have been invited to do so. I can tell you that we have had substantial consultations in the lead-up to this. But we had a good meaningful engagement with Palliative Care Australia. It was a good meeting.

Senator COLBECK—I think that is obviously reflected in the fact that there are some proposed amendments to the regs that have come out of that meeting. Again, I just go back to the point that, if the government is keen to have this measure passed, actively engaging with its constituency would be a positive way to progress that.

CHAIR—I do not think the department can make any comment on that.

Senator COLBECK—I am not sure about that. The department is being directed by the government to progress this process. The department is the agency that is there to interact and to engage and consult with those in the industry who are concerned about this. All that has happened is a letter, and out of a dozen people that the letter went to, many of whom have a significant interest in this and most of whom have submitted to us, they have had two responses from all the clients.

Mr Learmonth—We have had a substantial period of consultation and engagement with Medicines Australia and others. I understand what you are saying about Medicines Australia. We do not have a fleeting one-dimensional relationship with them. We talk to Medicines Australia regularly on a great many things, and I can assure you that if Medicines Australia has a particular concern they most certainly raise it with me or the secretary, as they have done in relation to

other things and as they do from time to time. They did not take the opportunity, as invited, to make a further response on this matter. They have no hesitation in relation to other things, as my experience suggests.

Senator COLBECK—I just find it extraordinary that the approach is to send them a letter and sit back and, if no-one comes back, that is consultation. I would not see that as active consultation—or interactive particularly.

Mr Learmonth—Again, it comes off the back of a substantial quantity of consultation in a variety of ways ahead of this.

Senator COLBECK—Yes, but if you are talking about the period of time that this measure has been considered—going back to 2005-06, when it was first considered—and what the actual different consultation processes were, none of them prior to the budget announcement went to the specifics of how the proposal might operate, such as has occurred particularly through this inquiry process.

Mr Learmonth—But after the budget in June we had workshops with Medicines Australia and GMIA and we went through in detail how the scheme would work, including in relation to waivers.

Senator COLBECK—But you did not give them the regulations, though. The regulations were not released until after—

Mr Learmonth—No, but that would have been unusual. But we went through the substance of what was reflected in the regs and how the scheme would work in substance in some detail.

Senator COLBECK—And yet they could not see the regulations. I mean, there is nothing like the document. We have had this discussion in a fairly detailed manner through our previous discussions. Were there any discussions with the industry generally about the period of time that they might have to consider the regs before responding?

Mr Busch—The letters did not prescribe any time to reply to them.

Senator COLBECK—So the letters went out on the 12th?

Mr Busch—The second one went out on 12 September, yes.

Senator COLBECK—So effectively two weeks ago. What would you consider a reasonable time for the industry to review regulations such as these and then come back with a considered response? How long do you think it would reasonably take to assess them?

Mr Learmonth—I think that would be an adequate period, given the nature of the changes from the previous one.

Senator COLBECK—Two weeks.

Mr Learmonth—Medicines Australia were well aware of the time frames of this. I understand they have appeared before the committee. They would understand full well what the time frames of the committee report were. I think that is more than enough context for them to judge what might be a reasonable time frame in which to put forward any comments. If they had any particular concerns, I would imagine that they would be hot on the phone to me.

Senator COLBECK—I did ask you at the last hearings about the cost recovery impact statement, I think.

Mr Learmonth—I think you did.

Senator COLBECK—Can you refresh my memory on that, because it is a question that came up again when I was reading through this documentation. What is the process for that under your cost recovery guidelines?

Mr Learmonth—I think the answer is that it is not actually done until the regulations are made.

Mr Busch—The cost recovery impact statement is certified by the secretary after the legislation and regulations are finalised, because that is the only time we can finalise. We are in a sort of circular thing—the secretary can only certify the cost recovery impact statement after we know the final form of the legislation and regulations. Then that statement is made publicly available.

CHAIR—Is that a new process?

Mr Busch—We are following the Department of Finance and Deregulation cost recovery procedures.

Senator COLBECK—I think it is a continuing process. No, I do not think there is any change in respect of that. What would be the time frame for that to occur? Obviously you have got to get to the stage of approved regulations and legislation being passed, but how long does it normally take to prepare a cost recovery impact statement? And what engagement occurs with industry as part of that process?

Mr Busch—The statement itself will have to be finalised and made publicly available before any implementation date. We are following the DOFD guidelines, and DOFD have provided us with advice about it.

Senator COLBECK—DOFD?

Mr Busch—The Department of Finance and Deregulation, sorry.

Senator COLBECK—So how long might that take once you get through all the hurdles that you have to? And what sort of consultation with industry is part of that process with the cost recovery impact statement?

Mr Learmonth—I am not sure we are certain about that. I will take that on notice, if I might. I think it is a relatively quick process, going, as Mr Bush says, after the legislation has been passed and before it takes effect. I can provide you with a time line on notice if you would like, or an indication.

Senator COLBECK—I would be interested to get some sense of a time line, because I do not think there is anything in the guidelines.

Mr Learmonth—I do not think there is. That is why we are struggling. I am not sure, but I think the guidelines are silent on this issue.

Senator COLBECK—I am certain they do not describe a time frame, but I am not certain about whether they describe a consultation process.

Mr Learmonth—Again, all this is contextual to if and when the House might pass the bill and when the intended implementation date is.

Senator COLBECK—I understand all that. I am just trying to save us doing it all again.

Mr Learmonth—We will see if we can provide you with some information.

Senator RYAN—Has the department looked back over previous rounds of submissions and considered what sort of number of submissions or what percentage of submissions would probably qualify under your consideration of the waiver rules?

Mrs Macdonell—It would probably be between 10 and 20 per year, I would think.

Senator RYAN—Out of?

Mrs Macdonell—We have about 90 major submissions and probably the same number of minor submission to PBAC each year.

Senator RYAN—Would it mainly be the major submissions that qualify for the waiver?

Mrs Macdonell—Not necessarily. If a drug is already listed and they are simply listing a new form, say for paediatric use, it could possibly be a minor submission.

Senator RYAN—The other question I have is about regulation 10, on the independent review fee. As I understand it, the independent review is conducted independently of the PBAC. I did not realise this was going to be included until I saw the regulations. What is the rationale for including a major submission fee for an independent review, because, as I understand it, it cannot overrule a decision of the PBAC or list a medicine of its own?

Mrs Macdonell—It would be a single fee. We would not want to give companies an incentive to go round the independent review route, so any fee they pay for the independent review would cover its further consideration by the PBAC. There would not be a secondary fee for consideration by the PBAC.

Senator RYAN—But the PBAC and the secretariat do not bear any cost of the independent review, which is conducted independently, do they?

Mrs Macdonell—No; it is borne by the department in another area.

Senator RYAN—Has the department sought advice on whether or not that poses an issue with the Australia-US Free Trade Agreement?

Mrs Macdonell—No, we have not, that I know of; I will have to check that for you. I am sorry; I do not know.

Senator HUMPHRIES—I am interested in the formula in clause 15 of the regulations. It deals with the waiver of fees. Under these regulations, the department may waive a fee ‘if the application involves the public interest and payment of the fee would make the application financially unviable’. Let us say we are talking about a drug which is ultimately listed, so by definition it does some public good or, in a sense, is in the public interest. But this drug is being lodged for application, and it is established that the payment of a fee would make the application financially unviable. Can you give me an example of a situation where, despite it being capable of being registered and despite it being unviable if not for the waiver of the fee, it would still not be in the public interest for the fee to be waived?

Mr Learmonth—I am sorry; could you ask that question again.

Senator HUMPHRIES—Yes. I am trying to work out what you mean by ‘in the public interest’. I will put it another way. Give me an example of where, when a person makes an application for a drug, you would consider it not in the public interest for the fee to be waived.

Mrs Macdonell—Drugs are ‘me too’. For example, if it were a class of drugs where we have five or six drugs listed in that class already and it would not necessarily be in the—

Senator HUMPHRIES—But you would not register the drug then. It would not be listed by the PBAC then, would it, when it got to the end of that process?

Mrs Macdonell—If it were demonstrated to be better or as safe and effective as a currently listed drug, yes, it would be listed. But it would not necessarily be in the public interest to have another one member of that group. So it would not be exempted or waived.

Senator HUMPHRIES—So it is a drug which is—

Mr Learmonth—If there were no net benefit in listing it compared to what was already listed.

Senator HUMPHRIES—So simply another drug which does the job as well as an existing drug in the marketplace. My impression is that these drugs are listed because in each case a new drug has some property or potential which an existing drug in the marketplace does not have and, if there is already a drug listed in the marketplace with the same properties, as it were, you will not register another one if it is already—

Mr Learmonth—Not at all. In essence, this goes to the nature of the cost-effectiveness assessment and thus the application that is made to the PBAC. A company will submit a drug for what is called cost effectiveness—in other words, they indeed are claiming a clinical or some other benefit in relation to the drug and thus a premium over its comparator, which would already be listed on the PBAC or some other form of treatment—or they might go for what is called cost minimisation, which means they are claiming no better clinical outcomes or benefit than another drug already listed and merely wish to list themselves at the same price as a comparator.

Senator HUMPHRIES—The question here is how you remove the uncertainty facing a company which is looking at listing a drug which, by definition, presumably has a low-volume market. The existence of the mandatory fee that has to be paid before you can even apply for the waiver may be a barrier to that company seeking the listing. If you are concerned about drugs that already exist in the marketplace but are just as good, and this is simply another one in that field, why not specifically exempt such categories of drugs from receiving an exemption, but say that other drugs, which are in the public interest and the refusal of an application for a waiver would make financially unviable, that these drugs, if they satisfy both those tests, must receive a waiver?

Mr Learmonth—I am sorry, could you repeat that again?

Mrs Macdonell—I think we said ‘may be waived’. We are currently in the regulations.

Mr Learmonth—I would like to hear the question again, sorry.

Senator HUMPHRIES—The uncertainty is obviously a barrier. We have been told by pharmaceutical companies, by Medicines Australia, that if they have a low-volume drug that they want to put up for registration then, on top of the cost of registering it, they have to also pay a fee, which may or may not be waived. Sometimes that just makes the application unviable. I want to clarify that by, in a sense, defining what is in the public interest and then saying: if it is in the public interest, and it will be unviable unless it actually gets that waiver, that it must receive a waiver.

Mr Learmonth—There are a couple of things to that. First of all, I do not think there is quite the uncertainty there as perhaps imagined. There was an earlier discussion in relation to the presubmission meetings, where companies or other interested individuals would be able to seek a view, from those who would make the decision about fees, well out from lodgement, as to their disposition. So I guess I take issue with the level of uncertainty there.

That said, the second issue is about how you might try and better define public interest. We have tried to set up a reasonably broad principle to allow discretion. My concern with trying to specify too much is that we can unwittingly exclude things. As you see quite often in legislation, in terms of a general or catchall provision, there is a broad principle for public interest and you try and apply that as best you can in the circumstances—bearing in mind that there are many factors that would bear on this decision, including the nature of the target population, how big it is going to be, the price of the drug that is required, and what else exists on the PBS or is otherwise available. So I think it is a little difficult to try and specify too much within that or you run the risk of creating a barrier that will have unintended consequences.

Senator HUMPHRIES—Well, the question is whether companies can get that satisfaction that their product will have a reasonable chance of being listed without a fee, if they are a marginal proposition.

Mr Learmonth—There is certainly the opportunity for them to do that at the presubmission meetings. I would imagine that that would give them more than enough. They would be speaking to the same people who would be making the decision about fees. They should have a degree of comfort from that, particularly if they were to go on to actually submit what they had discussed earlier and did not materially change it. They ought to have a degree of comfort in that. These things are, I suspect, not always fine judgements either, and a lot of these things with targeted small volumes—whether they be paediatric, palliative or Indigenous—are actually invited and worked upwards. We are very active in this space and we have worked a lot with those areas. I think that, for most of these cases, there would not be too much doubt, because we would be actively seeking and encouraging listings in these areas.

Senator HUMPHRIES—I will go and look at the *Hansard*. You obviously described how this will work in the earlier testimony today.

Mr Learmonth—Yes. But again, as I have suggested, Senator, companies or other interested people come along to a presubmission meeting before they lodge. They can do that and come and talk about any aspect of their submission—what their intention is, where they intend to pitch it, what sort of evidence they are going to produce, a range of things. We can have a discussion to try and help them improve their application or otherwise understand the process, and that would be the point at which they would talk about a waiver. We would get from them the same information that we would in relation to making the actual decision and give them a clear indication of what our disposition would be at that time. We help them through the process as best we can in these presubmission meetings.

Senator HUMPHRIES—Have you had any discussions with industry? You were talking with Senator Colbeck about what consultation you have had with the industry but have you had any consultation with the industry that would lead you to believe that there is a willingness or an intention on the part of pharmaceutical companies in this country not to pass on the net cost of these measures to consumers? We are imposing, effectively, an extra charge on the system of bringing a medicine to market. The expectation would be that, if a company has to bear a certain cost in relation to bringing a product to market, they will pass that cost on.

Mr Learmonth—I do not recall any specific discussion about that, I confess. We had a discussion about this at the last hearing, and I think I made the point that there are a great range of factors, both domestic and international, that go to the cost of developing a drug, marketing it, educating doctors around it and doing everything else necessary to bring it to market, and that the considerations as to price involve a range of matters above and beyond whatever the cost of production, development and marketing might be. There are a range of considerations that companies make about price points in given markets that have got to do with international comparisons, what they think is a point at which they are likely to get a positive answer—and a range of other considerations.

Senator HUMPHRIES—Are you saying that you believe that these costs will be absorbed by the industry rather than being passed on to consumers?

Mr Learmonth—I believe, in the scheme of things, several things, Senator. I believe that, in the scheme of what it costs to develop a drug—for example, the Medicines Australia website cites the figure of about \$1 billion to develop a drug, bearing in mind that a lot of these costs are spread across boundaries and across nations, and bearing in mind the range of the other costs that companies spend in bringing a drug to market, whether it be promotion, education, development and research, clinical trials et cetera—this is an extremely small amount of money in that context. There are a range of other considerations that companies take into account in deciding at what price point to pitch their drug in different markets, for that matter. In all of those contexts, it is just not possible to say that the costs of PBS cost recovery would, in a mechanistic way, be passed on. In any event, what the consumer pays in this country is regulated in terms of the copayment. So, in all of this, I think it is very hard to draw a link.

Senator FURNER—Just one quick question. On Monday we heard evidence from a witness that there is no net benefit in pharmaceutical companies paying the pharmaceutical benefits fees. What is your response to that sort of statement being made?

Mr Learmonth—The benefit is what they derive from listing on the PBS, which is access to a market they would not otherwise have.

Senator FURNER—So integrity and accountability—that is the benefit that they would get as a result of being involved in that arrangement?

Mr Learmonth—I am not quite sure what the thrust of your question is. Whether or not a fee is charged for the PBAC process does not change the essence of how PBAC looks at applications for listing and how those decisions are dealt with. There is most certainly an accountability and integrity to those and the charging of a fee for it does not actually affect the process of the PBAC.

Senator FURNER—I just wanted to get your response on those sorts of comments that were made.

Senator COLBECK—How far ahead of listing do prelisting hearings generally occur?

Mrs Macdonell—Did you say—

Senator COLBECK—A prelisting hearing.

Mrs Macdonell—Presubmission meetings—

Senator COLBECK—Sorry, wrong lingo!

Mrs Macdonell—It depends on the complexity of the submission. It is sometimes many months to a year out, but it could be as close as two or three months before they put the submission in. It is up to the company.

Mr Learmonth—They could have more than one submission. We talk with them at any point that they wish to talk about their submissions.

Mrs Macdonell—They make appointments to come and see us at any time they want to.

Senator COLBECK—I am just trying to balance what we were talking about earlier in respect of time frames with what they were saying to us on Monday.

Mr Learmonth—It is their choice: when and how many.

CHAIR—You were saying in that response that there is no limit to how many meetings you could have, so there is no limit per listing to one hearing?

Mrs Macdonell—No. They can come as often as they like.

Mr Learmonth—We talk to any of them.

Senator COLBECK—Is there a target implementation date? I understand where we are in respect of the overall measure, but do you have a target?

Mr Learmonth—That is all going to be subject to the disposition of the legislation.

Senator COLBECK—I know the initial target was 1 July, which we have now missed.

Mr Learmonth—Anything else will be a matter for the minister and the government in the light of what the House might decide in relation to this matter.

Senator COLBECK—Are there any specific consultation guidelines with which you are expected to comply on measures such as this?

Mr Learmonth—Not that I am aware of.

CHAIR—We do appreciate your time this afternoon and the way you have rearranged your schedule. Was there anything that we asked for that the department was going to get back to us on?

Senator COLBECK—I think there was one question that the department took on notice.

CHAIR—It would be good if you could get that as quickly as possible.

Mr Learmonth—We will get that to you.

CHAIR—And the question about the free trade agreement.

Mr Learmonth—Yes.

CHAIR—That concludes our committee hearings on the National Health (Pharmaceutical Benefits—Charges) Regulations 2008. Because of time—and I apologise to senators who have been waiting here—we are going to move straight into our next round of hearings. We will be

hearing from the Department of Families, Housing, Community Services and Indigenous Affairs.
I thank officials from the Department of Health and Ageing.

Committee adjourned at 4.12 pm