



COMMONWEALTH OF AUSTRALIA

# Official Committee Hansard

## SENATE

STANDING COMMITTEE ON COMMUNITY AFFAIRS

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

MONDAY, 22 SEPTEMBER 2008

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BY AUTHORITY OF THE SENATE



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**SENATE STANDING COMMITTEE ON  
COMMUNITY AFFAIRS**

**Monday, 22 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, Carol Brown, Bushby, Cameron, Cash, Colbeck, Jacinta Collins, Coonan, Cormann, Crossin, Eggleston, Ellison, Farrell, Feeney, Fielding, Fierravanti-Wells, Fifield, Fisher, Forshaw, Hanson-Young, Heffernan, 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, Siewert, Stephens, Sterle, Troeth, Trood, Williams, Wortley and Xenophon

**Senators in attendance:** Senators Adams, Bilyk, Colbeck, Fielding, Furner, Humphries, Moore, Ryan and Siewert

**Terms of reference for the inquiry:**

To inquire into and report on:

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

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**Committee met at 3.14 pm****DANIELL, Ms Donna Maree, Chief Executive Officer, Palliative Care Australia****SHAW, Mr Bruce Victor, National Policy Director, Palliative Care Australia**

**CHAIR (Senator Moore)**—I open this inquiry into the National Health (Pharmaceutical Benefits—Charge) Regulations 2008 consultation draft. The draft regulations allow for the charging of fees to applicants seeking to list an item on the PBS, under the NIP, or to amend a listing. I welcome representatives from Palliative Care Australia. Thank you for your submission. As you understand, there is a lot going on in the parliament today, so senators may be coming in and out. It is nothing to do with interest or concern about your evidence; it is just where we are. We have Senator Colbeck from Tasmania, Senator Adams from Western Australia, and Senator Furner from Queensland. They are going to be here for most of the time. I now invite you to make an opening statement.

**Ms Daniell**—First of all we thank the Senate Community Affairs Committee for the opportunity to speak to you again. It is most heartening that end-of-life issues are beginning to be recognised in health policy but they are potentially the oversight in this piece of legislation. Palliative Care Australia is the national peak body representing the interests and aspirations of all who share the ideal of quality care at the end of life.

Palliative care is a small market for drugs. There are about 40,000 to 50,000 patients in Australia cared for by palliative care services each year. There are about 100,000 Australians each year who actually die. Not all, of course, need palliative care or specialist palliative care services, but they are potentially the market for palliative care medicines. But we are very small. For this reason pharmaceutical companies do not see palliative care drugs as a priority when researching and marketing drugs—because of the small market and also the difficulty of doing studies of terminally ill patients. At our last representation here and in our submission we highlighted the precedent that the government has already set in funding the gathering of research data to support the evidence for drugs to be put on the PBS for palliative patients. That speaks for itself.

At the last representation we were saying that consultation was not as good and perhaps an oversight in relation to this piece of work. We are pleased to advise the committee that PCA has met with the officers of the Department of Health and Ageing to discuss the cost recovery arrangement. We are also very pleased that the Acting Assistant Secretary of the Pharmaceutical Evaluation Branch, Mrs Diana McDonnell, has confirmed to us by email that the department has taken on board our suggestions that more specific wording be included in regulation 15 dealing with the waiver of cost recovery fees for applications dealing with small population groups. They will ask the drafter to include words with the following meaning in the regulations as an indication of the type of application where fees could be waived. So we are very pleased this communication has come this morning for the committee's consideration. It says, referring to regulation 15, that they will put a further example that says:

Where the patient population is likely to be small and utilisation of the drug, medicinal preparation or vaccine is likely to be highly targeted.

This is the criteria for which the waiver of the fees would qualify. PCA is happy with this outcome. That is all I have for my opening statement, and we are happy to answer questions.

**Senator COLBECK**—Did you say that the communication from the assistant secretary of the Pharmaceutical Evaluation Branch had occurred today?

**Mr Shaw**—Friday.

**Ms Daniell**—I beg your pardon, it was Friday, yes.

**Senator COLBECK**—Can you give us some details on the consultation process with the Department of Health and Ageing—when, where and what the process was that brought you to meet with them?

**Ms Daniell**—Certainly. I will ask Bruce to provide the details.

**Mr Shaw**—We were sent the most recent consultation version of the regulations, along with their explanatory statement and a statement listing the changes in the draft regulations from that most recent version to the previous one. We noted with some interest that in the explanatory statement there was a reference to the extensive consultations that had been taking place with us and various other organisations. I sent an email on Monday last week saying that we would like these consultations to include something more than just sending out a bald letter, and that possibly a face-to-face meeting in which we could talk through some of the issues might be nice. They, to their credit, got back to us very promptly, and the result of that was the face-to-face

meeting last Friday morning, at which we spent half an hour or so talking through the issue. I came up with the suggestion that they could add an additional explanation at clause 15 of the regulations. They finally agreed to that and got back to us on Friday afternoon with that form of wording that they have, which we are basically happy with.

**Senator COLBECK**—So that is under the heading ‘waiver of fees’.

**Mr Shaw**—Yes. It is something short of a promise, but it is a strong indication that they would not consider charging fees for small patient groups—not just for palliative purposes but for any small patient group.

**Senator COLBECK**—Since we last met and the committee reported you received the initial draft of the regulations and then a week or so later, I think it was, the second draft along with an explanatory memorandum was provided.

**Mr Shaw**—Yes.

**Senator COLBECK**—Subsequent to that you contacted the department, saying you would like to meet.

**Mr Shaw**—Yes.

**Senator COLBECK**—But there has no approach from the department, only your personal approach to them.

**Mr Shaw**—That is correct. We initiated it, yes. Their letter certainly said ‘feel free to contact us’, so we did.

**CHAIR**—Mr Shaw, that was the letter that went out with the guidelines. Was that letter with the draft regulations that the department sent out for people to consider?

**Mr Shaw**—Yes, but we had already been sent it. It was the same one that they sent before.

**CHAIR**—Yes, it was subsequent to the hearing we had, subsequent to the process in which we advised all the people that these were the draft regs. And there was a letter attached to that. Is that right?

**Mr Shaw**—Yes.

**Senator COLBECK**—Are these words that you have noted in your submission today to go into the regulations or into the explanatory notes?

**Mr Shaw**—The regulations. The first bid was to put it in the explanatory statement or explanatory memorandum—and there is a difference there, I understand. We have been sent the statement, not the memo. But that was not acceptable to us because it does not really mean anything at the end of the day. I showed them section 15, where it could easily go—there was already one example there—and they agreed.

**Senator COLBECK**—Section 15 states:

*Example of circumstances in which a fee could be waived*

Listing change made because of a request by the Committee.

The suggestion is that the further words ‘where the patient population is likely to be small and utilisation of the drug, medicinal preparation or vaccine is likely to be highly targeted’ be added there as an additional example?

**Mr Shaw**—Yes. That was sent to us after the meeting we had with them, so I am not entirely sure whether they would need to reword section 15(2). It probably does not need to be reworded. It probably makes sense simply having the first point as:

Listing change made because of a request by the Committee ...

and then the second point being, ‘where the patient population is likely to be small and utilisation of the drug, medicinal preparation or vaccine is likely to be highly targeted’.

**Senator COLBECK**—One of the other things that we talked about during the hearings was the establishment of the special reference groups, particularly in respect of palliative care and paediatric care and some very positive work that had occurred over a period of time in reducing the number of indications that were off-list, so speak. Did you have any conversations with them about recommendations from one of those reference groups and where that might also be a reason to exempt an indication from these, given that that was the purpose that they were established for?

**Mr Shaw**—Yes. There is a palliative care medicines working group in the department that we are represented on, so that would be one of the reference groups. Am I right in saying that?

**Senator COLBECK**—I think there are two. There is one that has been established for about four years and one that has just recently been established. I think it was the palliative care one that has just recently been established. Is that right, or is it the other way around?

**Ms Daniell**—The Palliative Care Medicines Working Group has been going for four years. I have to say there is strong representation and there are strong links with the working group, through the secretariat to the PBAC—so there is strong support, which is probably why there was a non-articulated expectation that palliative care of course would meet the criteria for any very loosely worded waiver of fees, but certainly some sort of unspoken and undocumented understanding was not satisfactory for our population group, hence our need to really push to make sure that there are no barriers for industry or indeed individuals putting up drugs for consideration for PBS subsidy.

**Senator COLBECK**—To clarify: are the working groups informal bodies that make recommendations? How are they structured in relation to the PBAC? Their work is directed towards listing, obviously, because of the issues of using non-listed products, but what is their formal relationship?

**Mr Shaw**—Certainly in the case of the Palliative Care Medicines Working Group the secretariat for it is not from the pharmaceutical benefits area; it is from the palliative care area of the department, which is now part of the Ageing and Aged Care Division. However, the Pharmaceutical Benefits Division and all of the relevant branches of that are strongly represented around the table at the Palliative Care Medicines Working Group. They provide excellent reports on usage—data reports, for example—of palliative care medicines under the PBS. They did not, for example, think it was necessary—it had not occurred to them, clearly—to provide a consultation brief to the Palliative Care Medicines Working Group on this legislation, even though the last meeting of the Palliative Care Medicines Working Group was in fact in July, just a little bit before your hearings. It came as a bit of a shock to them that we wanted to put it on the agenda to discuss. We did actually spend most of that last meeting discussing it, but it was because we had put it onto the agenda.

**Senator COLBECK**—So it is effectively a committee of the agency, not anything that has got any direct links.

**Mr Shaw**—It is not a committee of PBAC; it is a committee of the department, yes. But it does have a right, through the department, to report and make recommendations to PBAC and, I guess, to the minister through the department. I am confident that in the future any such changes will be the subject of consultation—it will be consulted about any changes to the PBS regulations or legislation that might affect palliative care, I am confident, in the future.

**CHAIR**—It is on record now, that is for sure. Your confidence is on record.

**Mr Shaw**—Yes.

**Senator COLBECK**—Hesitantly confident perhaps?

**Senator SIEWERT**—Now you are qualifying it!

**Senator COLBECK**—It sounded hesitantly confident. What I am trying to establish, though, is what specific role these groups play. I understand and I applaud the reasons that they were set up by the department. I do not have any issues with that at all. I think that the work that they do should be recognised in some way through some sort of linkage, but it concerns me that, when there is a fundamental change to the way that the system is going to operate that may impact on that area, they are not in the loop. My question there would be: how would you establish or reinforce or maintain the link so that those things, as we often say, never happen again? That would be a concern that I would have.

**Mr Shaw**—There are terms of reference for the Palliative Care Medicines Working Group, which I am sure the department could provide to you or I could send to you if you wanted. As far as I know, they are public documents. I am just not sure off the top of my head how they talk about consultation, but it is possible we could add another subclause to that to say that the department should consult with the palliative care sector through the Palliative Care Medicines Working Group on changes to the PBS legislation which could affect access to medicines.

**Ms Daniell**—We would welcome the opportunity to align that piece of work, the Palliative Care Medicines Working Group, more formally with the decision-making process—if, in effect, in being able to support the administration of those new wordings there was a formal understanding that the medicines working group would be asked for advice and there was a formal link back to the PBAC, so it was not ‘mood of the day’ bureaucracy; it was actually something that was documented so that we did not have to revisit this again.

**Senator COLBECK**—That is what I am trying to get to. As I said, the two groups that are established (a) were needed and (b) have had some effect. But it is probably even more important that there is some way to link those groups back and particularly pick up some of their recommendations as part of this process. There needs to be some reference in the regulations or the guidance notes that work with the recommendations to recognise that the working groups exist and to take some sort of notice in the fee-setting process that their work has some value; otherwise that link basically does not exist. The regs themselves would be a fairly obvious place to do that. When I went through the regs, I made a comment under item 15 that it could include recommendations from reference groups, which would actually pick up what you are looking at. Your recommendation is probably slightly broader, but this would be an additional listing point that could be added. It would alert people making these considerations to the reality of the working groups, which is very important to this whole process and is really the reason we are sitting back round the table today. The concern that these minor use groups exist is the reason that we are still sitting here.

**Ms Daniell**—From our point of view there is great wisdom in linking up, making it more formal and utilising what you are investing in. There are some considerations, though, that the department will advise on about the duration of funding for the working group and that type of thing. But that is just a small issue that can be addressed to make sure that all arms are working in harmony, and we would welcome that.

**Senator FIELDING**—Thank you for your submission. I know there have been fairly short time frames again and I appreciate your efforts. One of the submissions the committee received referred to a speech of mine in a second reading debate. I asked:

... will there be some drugs in the future that will not be available for vulnerable Australians because making applications to get those drugs on the PBS could be cost prohibitive to the company applying? That would be of concern especially in Australia where we have a sense of a fair go.

That is the area that you have homed in on and had further discussions about. I may still think it does not go far enough, but I appreciate the attempt that you have made to address that issue. The cost recovery principle is a real concern for a lot of people. It seems to have some merit, although some may argue that it does not. The issue is that we do not want some vulnerable Australians to miss out because of this change. That is the real concern. Obviously your link to this through the area of palliative care means you are really concerned about it. Did you think of going any further than you have? It definitely has to be addressed in legislation. The EM makes us feel all warm and fuzzy, but it needs to be in legislation. Do you have any more suggestions that go further?

**Ms Daniell**—Our comments have been constrained to the scope of the legislation. We are quite satisfied that, by enabling industry or others to come forward with the evidence they have—it is costly getting the evidence; we must recognise that—they will be able, without too much paperwork, to very easily get the exemption to enable access for this vulnerable group. However, there is another thing about removing the barriers that is not about legislation but about good communication. I think there is an opportunity to work with other partners to make sure everyone well understands the type of early consultation that industry and others can have with the department before they start investing and getting the evidence together. That way we can short-circuit the whole process. There needs to be a whole lot of communication to make sure everyone in the field understands how to go about it and what the fastest and most efficient way to get the right outcomes for this population group is. I think all too often people do not understand that. Too much time, money and energy is being wasted, and we would encourage the department to be more open, have more consultation and educate all players to achieve the outcome that is needed. There is certainly a gap there, but there are a lot of players that can facilitate closing it.

**CHAIR**—Are there not already prelisting conferences available to all the parties wishing to look at whether they are going to list or not? Do you not think that the prelisting conferences that are available now would serve that purpose?

**Ms Daniell**—My question would be: how far does that go—to the smaller players or is it pitching just to the bigger ones?

**CHAIR**—The way it is publicised anyone who is looking at putting something into the process has the option to have that discussion with the department.

**Ms Daniell**—Yes.

**CHAIR**—It was my understanding that was the step. You do not have to do anything. You do not have to list. You can have a conference with the department before you do.

**Ms Daniell**—Certainly, that is how we were briefed. That is the goal and we would like to see that. We would like to see evidence that people are taking up that pre-session to sort themselves out before things get started.

**Mr Shaw**—In our discussions last Friday with the department they made it very clear that that option was to be encouraged. They said that anyone can call us and come in and talk about what sort of market they are looking at and the possibility of waiving fees.

**Senator FIELDING**—Do you think that addresses the issue? You may not have had a chance to look at the Medicines Australia submission on page 4. I will quote the bullet point. It is subjective, I know, but I do not think it is out of context because I think the page before that says on fee waivers ‘the risk can be articulated as follows’ and then there is a colon and the third bullet point, so I think it stands in its own right. It says:

The risk can be articulated as follows: ... Whilst the regulations provide for full or partial fee waivers where this is in the ‘public interest’ (as determined by an Officer of the Commonwealth), the decision on whether a waiver is granted will only be made subsequent to a lodgement of a submission. Such information will not be made available prior to the decision to prepare a submission.

In other words, you have to do one before you get to the waiver situation, so it is the cart before the horse. If you want to do a waiver, you cannot get to the cart until you do the horse. Do you have any comments on that because you must have been through this a bit?

**Ms Daniell**—I believe Medicines Australia’s advice was prior to this new provision and so from a legislative framework and consultation we believe that it was well aware that small population groups will clearly be considered. It is not a straight through, but I believe that there will be no problems with industry and stakeholder groups understanding what the parameters are for a small population group and it does address the barrier that was there before.

**Mr Shaw**—It is a conundrum. What the department indicated to us was that they would not in all likelihood impose a fee for a pharmaceutical whose target group was a small group and that was the indication that was being sought. However, they could not give that undertaking until the lodgement had been made, the application had been made. So there is a bit of faith involved, but it was a clear statement of intent on their part that it would not be the intention.

**Senator FIELDING**—I appreciate the background you gave. There were a couple of good examples there, I think. They are pretty real from what you can see. From that point of view, that shows the issue that someone might miss out if it could not be potentially waived. I need to be mindful how I say this so I do not offend, but I think it is always nice to know that you have an elected official to take the final decision—and not even the final decision—someone to appeal to rather than unelected people who you cannot really get to, if you know what I mean—the ‘not us, it’s them’ thing when the minister says: ‘It wasn’t me. It was them.’ I tend to think that having the minister with the authority or the minister to retain discretion to waive fees allows at least some public pressure to be applied on these things rather than it being said, ‘That is the final decision.’ I know there is an appeal process—do not get me wrong. I know that the process is there but it is really all in the system and not any public issue.

**Ms Daniell**—I think precedents would show that there is positive and negative in ministerial and bureaucratic decision making. I think that was just being able to say what the precedents are across the whole of health. It would not be good to start something new, necessarily, in this space.

**Senator FIELDING**—Something that is not new, that has been done before.

**Mr Shaw**—The system at the moment is said to be independent of government, of political pressure, if you like, and introducing that sort of process could well change that balance. I think you would need to think about it carefully before going down that track.

**Senator FURNER**—I am wondering about the patient population, 40,000 to 50,000, that you have indicated. As a proportion of the population previously, has it always been around that figure with respect to the present population or has it been a growing amount over a period of time?

**Ms Daniell**—If we were looking at health economics and the projections for the palliative care population, there is increasing recognition of evidence that the medicine supplying which was traditionally used for end-of-life issues with cancer management is now supporting ageing issues, end-of-life chronic illnesses. So there are a range of drivers that may increase the population where palliative care medicine applies. However, I do not think there are major drivers for increasing the number of deaths per percentage population; I think that is quite capped. Unless we have some radical new illnesses coming into play, the portion is growing with the

type of illnesses. At the moment, we have 132,000 Australians that die every year. About 100,000 of those are those with an expected death trajectory, so that is where the palliative medicine potentially applies. About half of those people who are currently cared for through contact with specialist palliative care based on their needs. So there is certainly no major driver to shift this population group into a large population group.

**Senator FURNER**—I am trying to establish what you define as small to large, basically. Obviously, you consider yourself as a small organisation. You certainly touched on one thought I had with regard to ageing. We have an ageing population; therefore, I would have thought that that figure would naturally grow over time.

**Ms Daniell**—There are the ageing dilemmas. But the scope for when palliative care medicine applies and the end-of-life issues usually involve less than 12 months. While we are all ageing and the proportions will change, it is not, for example, that a patient will qualify for many years of therapy under that type of drug and those criteria.

**CHAIR**—Thank you very much for coming to see us again. I am sure we will see you again fairly soon. Thank you for your time and we do apologise for keeping you waiting.

[3.42 pm]

**VINES, Mr Timothy, Private capacity**

**CHAIR**—Welcome. You heard my comments about senators coming in and out.

**Mr Vines**—Yes, thank you.

**CHAIR**—I always like to reassure people that it is nothing to do with their interest; it is a busy time in parliament. Do you have any comments to make on the capacity in which you appear?

**Mr Vines**—Presently, I am an honours candidate in the area of health law and I am research associate for Associate Professor Dr Thomas Faunce, who appeared at the previous inquiry into the legislation that would set up these regulations. He is a lecturer at the Australian National University in both the College of Law and the College of Medicine and Health Sciences. Also, just by way of capacity, I have assisted Associate Professor Thomas Faunce in drafting several journal articles relating to the Pharmaceutical Benefits Scheme and the PBAC which are to be published in the Australian *Journal of Law and Medicine*. In September, I attended an ARCS Australia conference which was titled ‘A practical update: the PBAC guidelines’, where I had the opportunity to speak to representatives and health economists from industry and from the Department of Health and Ageing.

**CHAIR**—I know you have information on parliamentary privilege and I know you were here with Professor Faunce at the last hearing. We have the joint submission that you put in with Professor Faunce. I invite you to make an opening statement and then we will go to questions.

**Mr Vines**—First, may I extend both Associate Professor Dr Thomas Faunce’s and my own appreciation that we have been given a subsequent opportunity to appear before the committee, and thank you very much, Madam Chair and Senators, for taking time to listen to our submission and to read through it. Hopefully, you have had a chance to read through the written evidence and I will only summarise it here rather than go into detail about it. However, if you have any questions, I am more than happy to try and answer them for you.

As we say in our submission, the Pharmaceutical Benefits Scheme is one of the crucial elements of Australian health policy. It is an institutional representation of the notion of a fair go. As a vital component to it, we seek that the PBAC remain independent and sustainable into the future and, as part of that, it should remain independent of both government and departmental interference. On balance, having considered the regulations as put forward, we think that they present an adequate balance between ensuring that the PBAC is sustainable and viable into the future and, at the same time, representing if only a symbolic contribution by the pharmaceutical industry to an area where they do receive financial certainty, as the Department of Health and Ageing submission put, and also financial reward for bringing life-saving medication to Australia. I certainly would not want the committee to feel that our submission in any way lessens our gratitude to the pharmaceutical and generic industries for providing much needed medicines to Australians.

We feel that the sustainability and integrity of the PBAC would be best assured by ensuring that the revenue raised by this measure is eventually directed back to the PBAC. Dr Thomas Faunce, at the previous Senate hearing, discussed how the PBAC members were interested in ensuring that post-listing surveillance was something which they could consider and ensuring that the indications listed for a PBS listed medication were the ones that were most appropriate.

If I may, just briefly before concluding, I will turn to the thoughts of the senators, which played an integral part in the new submission that we put in. There was concern that there was not enough consultation, both with industry and with other stakeholders. While more time has been devoted to investigating these regulations—and thanks go to Senator Fielding for ensuring that there was a short, sharp inquiry—the cost recovery regulation and cost recovery ideas have been considered since the 2005 budget. While they were subsequently dropped, the industry was put on notice that this was certainly a direction that we were moving towards, and with 15 years of cost recovery mechanisms for the Therapeutic Goods Administration there was at least a precedent there for cost recovery in a health policy area.

Orphan drugs were another reasonable and legitimate concern raised, and hopefully the proposed regulations address that, specifically by way of the exemption in clause 14. The same goes for low-volume drugs, where the fee waiver exemption in clause 15 can be either partial or whole, and the option for internal review ensures that needy Australians—working families, pensioners and other concession card holders—are able to access necessary medication.

Finally, we come to the cost to low-income earners and families and the risk that needed medicines will not make it onto the Australian markets, that these cost recovery mechanisms will in some way act as a deterrent. There are a couple of points on that—firstly, whether or not the figure is agreed to. It has been quoted at \$17 billion for the Australian pharmaceutical industry, and as a member of the House of Representatives said during the second reading stage of this debate: ‘The pharmaceutical industry in Australia shares in \$4.6 billion of reimbursement under the PBS system, which costs the government \$7 billion and the Australian taxpayer about \$1.5 billion out of that.’ So there is a significant financial reward and financial certainty for the industry in listing a medication, and the proposed fee schedule would constitute a relatively minor financial inconvenience to companies seeking to list a medication on the PBS.

To add to that, an article which discussed the Gardasil listing mentioned that, in 2006, 47 per cent of major submissions were rejected by the PBAC. It has been suggested that this is because the PBAC process is not transparent, and certainly I will admit that when I was at the ARCS Australia conference this was a view that was expressed by industry—that the PBAC process is not transparent. The government will respond that the costing of therapeutics is not transparent. But, anyway, 47 per cent of major submissions were rejected by the PBAC. This may be a question of the poor drafting of submissions, and perhaps attaching a value to the submission that we are listing would give pause to therapeutic and pharmaceutical companies before putting in a submission to ensure that it actually conforms to the cost effectiveness and cost minimisation guidelines and specifications set down in the PBAC guidelines that are referred to.

**CHAIR**—Thank you very much. Senator Humphries.

**Senator HUMPHRIES**—You say in your submission that you believe that the capacity created in the regulations to exempt certain classes of medicine from a fee should address the concerns that were raised by senators on an earlier occasion. I put it to you that the concern remains that for low-volume drugs which are not caught by the exemption in the first part of clause 14, there is still a doubt in the minds of the companies who would bring forward such applications as to whether the very considerable cost of making that application was not actually going to be added to by an application fee being imposed on that company. My reading of the regulations, for example, is that a company does not make an exemption application until the application itself is lodged. So they have actually had to go through the process of preparing the application, which can cost several hundred thousand dollars, putting that on the table with the department and then asking for the exemption. Is that your reading of the regulations?

**Mr Vines**—I think that that is certainly a reasonable reading of the regulations, and I note that Senator Fielding raised that concern earlier. The Medicines Australia submission puts the figure of creating a submission at up to \$500,000 for a major new drug and a major submission. What I would say to that, though, is that Australia is not the only market for therapeutic goods and medications. While in 1999 Australia was one of the few countries that had a cost-effective analysis as part of its reimbursement agency, this has now spread to England. Canada has been looking at it and, as Dr Faunce, said in the previous submission, if a Democratic presidential candidate is elected next year it is quite likely that they will review the prohibition in the United States legislation on cost-effective analysis. What I am saying is that pharmaceutical companies should perhaps move towards international harmonisation of these submissions. That is currently underway. I know that there are international working groups on this. So if they get not backed by Australia they may not get knocked back by England. Then the submission will not be a total waste of half a million dollars. The regulations allow for an application to be withdrawn if they decide not to appeal the decision or if they consider the fee to be excessive. Hopefully though—

**Senator HUMPHRIES**—Can I interrupt you there. It may be that in some point in the future there will be some capacity for companies to harmonise their applications, but at the moment the legislation in all of these countries is different and the companies themselves say that they have to incur those quite independent and substantial costs in respect of each application that they make, particularly when they are talking about different indications for a drug that is already in the marketplace. So assuming that we accept that that evidence is valid in the present circumstances, why wouldn't a company hesitate to apply for the registration of a low-volume drug if they could not be sure about a waiver until after they have actually made the application and incurred the fee?

**Mr Vines**—I suppose part of that goes back to what was said earlier in the committee about the revenue raised from these cost recovery mechanisms going to enhancing the pre-listening and pre-lodgement process. So even before the clinical trials are run it would perhaps allow for more resources, for pharmaceutical companies to meet with the department to have a conference and discuss the process that is set out.

**Senator HUMPHRIES**—But there is no indication in these regulations that there is any provision for that, is there? That is an ideal but it is not there in these regulations or in the legislation itself.

**Mr Vines**—No. That is certainly right. It may be the subject of later departmental policy or amendments to the regulations, but from my reading you are correct.

**Senator HUMPHRIES**—Clause 15 of the regulations says:

The Department may waive a fee or part of a fee payable under these regulations if the application involves the public interest and payment of the fee would make the application financially unviable.

Thinking about an application to register a medicine on the PBS, clearly there must be people in the community who want to use that medicine for whom there would be some relief of the symptoms of a condition or illness by virtue of there being that medicine available to them. Given that that is the case, can you conceive of a circumstance in which the registration of a medicine would not be in the public interest?

**Mr Vines**—If I may just take you back to the comments of Mr Francis Sullivan from the AMA in the first committee hearing, he said that the supply of PBS medicines is more than a business decision. It is fundamentally about what is best for patients and what is fair for taxpayers. At the heart of the PBAC process is a cost-effective mechanism and I think, as perhaps the Gardasil experience has demonstrated, where the PBAC came out with an initial negative reaction, the public do not like having cost-effectiveness at the heart of decisions about medicines, especially lifesaving ones. The situation perhaps would warrant a public interest waiver where there was no medicine for a treatment currently on the PBS. But if there are already medicines there then it would not be in the public interest for a more expensive drug with only a marginally incremental benefit to be listed at a significant cost to the taxpayer. The public interest is both the interest of the patient and the interest of taxpayers, who will either through co-payments fund the \$1.5 billion or through their general taxes fund the remainder, the \$7 billion of the PBS process itself. I do not know whether that answers your question exactly—

**Senator HUMPHRIES**—Can I rephrase my question. Why shouldn't the regulations say that the department must waive a fee if the application involves the public interest and payment of the fee would make the application financially unviable? Why should there be any discretion at all if there is public interest there and application fee has to be waived, otherwise it will not be financially viable to proceed?

**Mr Vines**—That is a good question. Personally speaking here, although I am not sure what Dr Faunce's opinion would be on that matter, I think it should be established practice that where a drug that is seeking to be listed can demonstrate significant public interest behind it or public benefit that is deserving of a waiver then that is where the investigation should stop. It should then be a question of what level of waiver. That may be what the 'may' is there for: to allow for degrees of waiver.

**Senator HUMPHRIES**—One last question. Wouldn't you agree that if a company has prepared an application, let us say for a new application of a low-volume drug, and they have gone through the cost of preparing the application, they have made the application, and their request for a waiver has been knocked back. Given that the costs are mounting for a low-volume drug, the likelihood of an applicant than proceeding to potentially throw good money after bad and proceed down the path of an appeal is very small. Wouldn't most companies be likely to say, 'If we are not going to get the waiver, we'll cut our losses and just walk away from this drug'?

**Mr Vines**—I suppose the difficulty in answering this question is that we are not sure what the indication is that they are seeking or any restrictions that they are seeking on the listing. As I mentioned before, the fact that there is a fee that is now payable might have given them pause to think that they are asking for either too narrow a restriction or too broad an indication and that if they came back to the PBAC with a more appropriate restriction then they would be more likely to get through.

**Senator HUMPHRIES**—But they have got to pay another fee for that, haven't they. If they are already refused a waiver, they have to pay another to get that second application up.

**Mr Vines**—Hopefully they would not have pushed it at that stage to have paid the fee; they would have entered into a discussion beforehand with the department, seeing that they had already invested all this money in conducting the clinical trials. The appeal process, both internal and through the Administrative Appeals Tribunal, is at least less costly than through the ordinary courts.

**Senator FIELDING**—You have a lot more faith than I have, mate, I can tell you. I thought it was fairly interesting that you drew a highlight out that the PBS is estimated at a total cost of, I think, \$7 billion for 2007-08—

**Mr Vines**—That is right.

**Senator FIELDING**—and you have put the revenue expected to be raised through cost recovery at \$9.4 million. I have read your submission, and I have to say that you have a heck of a lot of faith, given that the actual revenue raising for the government is such a small amount—it gets to be in the cost. I think we should be very careful when it comes to Australians potentially missing out on some drugs because of the cost-prohibitive nature of the cost recovery of applying to get those drugs on PBS. You have a lot more faith than I have in this system. To be frank with you, given that the gain is \$9.4 million, I think we need some real good assurances about cost recovery. You seem to dismiss that quite easily in your submission. I think you argue that adequate allowance has been made in the draft regulations on this waiving. I think we saw the inference in questions before that it still seems to be pretty ambiguous.

**Mr Vines**—As I was saying to Senator Humphries, I suppose one of the difficulties about talking about whether low volume medications will be knocked back or denied is the fact that we have not yet had any scenarios put forward, certainly not by any of the submissions that I have read through, about actual cases where pharmaceutical companies have said, ‘No, that’s it; we’re pulling out of Australia.’ I appreciate your fears, and they are reflected as well by the voices that I heard at the conference I attended in September by industry. If I can clarify what I said in the submission, the proposed clauses 14 and 15—14 allows for an outright exemption and 15 allows for a full or partial waiver—do accommodate the areas of most concern to senators when it came to ensuring timely access to lifesaving medicines, which of course is underpinned by the National Medicines Policy.

One comment that I did make in my submission, which perhaps I should reiterate, is that where in the regulations it talks about the public interest that should probably be seen in the light, hopefully by the department and by administrative appeals tribunals, if it ever reaches that stage, of reflecting the National Medicines Policy. That is what underpins the National Health Act and these regulations. So that is all about timely access. But, as I said earlier, the Therapeutic Goods Administration have had full cost recovery measures for 15 years and, as the Department of Health and Ageing submission said, they still have new medicines listed. But I note your very valid concerns that Australians may miss out. But certainly that would be something that would come up during any review of these regulations in the future.

**CHAIR**—Thank you, Mr Vines.

[4.03 pm]

**SULLIVAN, Mr Francis, Secretary General, Australian Medical Association**

**CHAIR**—Welcome. You have been here before?

**Mr Sullivan**—I have.

**CHAIR**—So you have the information. We have your submission; thank you very much. If you would like to make an opening statement we will then go to questions. I have been telling witnesses about the senators needing to move in and out.

**Mr Sullivan**—Thank you once again for the opportunity to appear before you today. Firstly, the AMA would like to reiterate its concern about the government policy to introduce cost recovery for the Pharmaceutical Benefits Advisory Committee process. There is no net benefit to the Australian people in requiring pharmaceutical companies to pay application fees for PBS listing processes. These companies will simply factor this cost into their listing prices and claim them as legitimate business expenses for tax purposes. The potential consequence for the Australian people is that companies will decide there is no business case to bring a low-volume, low-priced product to the Australian market. These will be medications for small populations, medications for palliative care, oncology and our Indigenous Australians, for example.

The draft regulations that the committee is considering today do not allay our concerns. This is because, for applications for new listings and new indications or major applications, companies will have to pay \$119,500 upfront. They will have to make this payment knowing they stand only about a 60 per cent chance in getting the listing approved. According to the information on the Department of Health and Ageing's website in 2007, 41 per cent of the major applications considered by the Pharmaceutical Benefits Advisory Committee were not recommended for listing. So 41 per cent of the applications that will attract the highest application fee did not get listed in 2007. That is why in our submission we have recommended that waiver decisions be made by the minister, not the department, and that the decision be tabled in parliament.

If the policy intention of the PBS is to be maintained, then the AMA believes the public interest test in the waiver provisions in the regulations must be considered by the minister. This will ensure that the minister has direct responsibility for personally considering the short- and long-term public good issues. The consequences are important. This should not be delegated to non-elected officials. It will also make the decision transparent. We believe this will give companies some certainty that, where there is marginal financial viability with their applications, this will be considered at the highest levels. It will give the Australian people some certainty that the greater public good is at the core of the decision.

**Senator FIELDING**—Thank you for your submission. I am sorry to rush this, but I have to get back in the chamber. In respect of the draft recommendations, the AMA states:

- the Minister, not the Department, should make waiver decisions about the payment of lodgement and listing fees;
- the Minister's decisions about waiver applications should be tabled in Parliament ...

Could you outline the rationale or the reasons for those statements for me?

**Mr Sullivan**—Yes, and we could pick up on it from the questioning of the previous witness. Obviously, our view is that ultimately this is a public interest test. The public interest test, as has been said, has many aspects to it. Ultimately, it is a political decision—the decision to take an application forward. There is not much point in having an application process go through the many hoops the departmental processes will take it before you get a chance even to say, 'Can it be waived?' Rather, if a company makes the case to the minister that it is in the interests of a group in the population or more broadly then the minister can decide whether this application has merit not to attract the fee. A profound decision like that would need to be transparent. Because the minister is making it, the minister can table the reasons in the parliament. That is our thinking here.

Obviously, as I have said, it is in the context that we are concerned that a cost-recovery mechanism generally has too many risks for some individuals in the community at certain times. It is the 'some individuals at certain times' that requires a political judgement that needs to carry weight both in responsibility and in consequence. That is our thinking.

**Senator FIELDING**—Thank you. I have to go, unfortunately.

**Senator COLBECK**—I will pick up from where Senator Fielding has left off. Your submission is basically saying that you do not believe the draft regs adequately address the overarching concerns. In going down the

track you are talking about—where a minister might actually grant the waiver and there is that process that is taken out of the bureaucratic arm of government, if you like, that provides some accountability—we are not talking about them automatically giving access to the PBS for the drug. Effectively, what we are saying is that for the purposes of this particular indication, there will not be a fee being charged. It is not detracting from the efficacy of the PBS system or the PBAC at all.

**Mr Sullivan**—No.

**Senator COLBECK**—Effectively, what it is saying is, ‘For the purposes of this particular indication, we’re not going to charge a fee for that process.’ Now whether it is based on some of the other issues that we talked about before, a recommendation from one of the working groups or something of that nature, that would, in your eyes, provide a significant improvement to the process as has been discussed at the moment.

**Mr Sullivan**—Yes, what is on the table before us—the regs—our view is that the process to achieve a waiver needs to occur directly to the minister because of a public interest test. If we go back to first principles here: the fee is a disincentive, so then to have the fee removed should be removed on public interest grounds rather than on asking the PBAC to make a judgement. The PBAC has a process of integrity based on the principles of the PBS, and we believe let us leave that in its integrity. The question about whether the fee is a disincentive, and it may be a disincentive for a benefit for the public, is a decision that needs to be taken away from the PBAC and taken by the minister. It is not about waiving the fee automatically means that the application then will be successful, and I think that is a very important distinction you are making.

**CHAIR**—It seems to me that this is an element of a payment, and one of the things that we have consistently talked about in this particular field is maintaining complete independence so that there is no way that political pressure or lobbying or personal views can impact on a final decision through the process because there has been so much over the years where these decisions are very difficult. And if we have always kept the political aspect out so that the minister only receives recommendations, and that is their role, at any level including a ministerial discretion, which this is, would seem to me to be a step in term of creating a dependence rather than total independence. That is the core difference in the views. It would be useful if we could get your—the AMA has been very clear that they do not see that conflict and it would be good to have your response to that question on record, Mr Sullivan.

**Mr Sullivan**—I think we are confusing two processes. I think the AMA is very clear about the need for no political influence over the listing of drugs on the PBS. We are not talking about the listing of the drug on the PBS; we are simply talking about an identified financial barrier to particular potential drugs with particular potential benefits for particular people in the community. A financial barrier to the companies going forward to engage in the rigorous, non-political process of achieving listing on the PBS. I think we are very clear we are talking about two distinct processes. We certainly do not believe that the process we are suggesting about achieving the waiver in any way creates a precedent that can somehow cross over into the process about achieving listing on the PBS for a PBAC. We see them as two distinct issues.

**CHAIR**—I just wanted to get that clearness on the record.

**Senator COLBECK**—Basically, I think we are on the same track. Can I go back to your interactions with the department since the last hearings and in particular since the report came out? What communications has there been between the AMA and the department in respect of the issue of initially the draft regs and then the second incarnation that had the explanatory notes attached?

**Mr Sullivan**—We received those from the department by way of its normal dissemination of information. I have not had direct dealings with the department. We have not had any interaction with the department in the interim.

**Senator COLBECK**—Were there any specific requests that came with the documentation? You were basically just provided with that as part of an information process?

**Mr Sullivan**—It is my understanding that it is the latter: the dissemination of information from the department.

**Senator COLBECK**—So it could not be called a consultation process.

**Mr Sullivan**—We have not been consulted per se. Like many groups we have been watching the political debate in the Senate and we responded accordingly to this process. Therefore our understanding of how things will work is the same as everybody else’s.

**Senator COLBECK**—So your response has effectively been to this committee process rather than necessarily the department or the government at this particular time?

**Mr Sullivan**—That is correct.

**Senator COLBECK**—You say that the draft regs do not adequately address your concerns. Fundamentally, can that be changed or do you have a basic view that cost recovery is not the process to be undertaken with respect to this particular measure?

**Mr Sullivan**—Yes. In the spirit of the AMA's engagement we are trying to make something we think is not so good maybe slightly better. As we said in our first submission and I tried to reiterate, we do not believe cost recovery should apply in this field.

**Senator COLBECK**—I will leave it at that, thank you.

**CHAIR**—Mr Sullivan, in your experience have you had access to regulations like these before primary legislation has been passed?

**Mr Sullivan**—In the 15 years that I have been doing this sort of work, Senator, have I had access to the regulations before primary legislation has been passed? Probably not.

**CHAIR**—To me it is a first in terms of the process. I think it is a good thing but because you have been playing in this field a long time it is good to get on the record whether you have seen regulations before legislation.

**Mr Sullivan**—Since we are on the record, I am working in this field rather than playing.

**CHAIR**—Working hard in this field, Mr Sullivan. Thank you. I do apologise for the semi-rush; we are on a tight time frame, as you are, I know.

[4.18 pm]

**BRUCE, Mr Andrew, Reimbursement Strategies Manager, Medicines Australia**

**DELAAT, Mr William Louis, Chairman, Medicines Australia**

**SHAW, Dr Brendan Antony, Executive Director, Health Policy and Research, Medicines Australia**

**CHAIR**—Welcome. I know you have information about parliamentary privilege and so on. We have your submission; thank you. We have been speaking with your CEO, who has passed on his apologies for not being here this afternoon. He was very disappointed that he could not be here, but the time frame you know is tight. Would any or all of you like to make an opening statement and then we will move to questions?

**Mr Delaat**—On behalf of Medicines Australia I would like to make some introductory comments. Thank you for the opportunity to appear before the committee on matters pertaining to the proposed additional charges to pharmaceutical companies. I must put on record that Medicines Australia is dissatisfied with the very short time that stakeholders have been afforded to consider the draft regulations under review. I am speaking both about the discussion with the department and with particular reference to this Senate committee review.

We find it very difficult to understand why the government believes that using such a compressed time line is conducive to good public policy making in a democratic society. May I respectfully remind the committee that interests of Australian patients are worthy of genuine consideration here, and so are our 50 member companies. Whatever resources our companies may or may not have at their disposal, we deserve to be treated fairly when it comes to concerns around policies that affect our industry. Maybe this is something that the committee would like to comment on when it hands down its findings.

Turning to the pressing matters at hand and the detail of the legislation, in its submission Medicines Australia has provided the committee with detailed critical commentary on the draft regulations. It has also provided the committee with a series of recommendations and amendments required should the government wished to ameliorate the very predictable effects of what at heart is a piece of poorly conceived policy that threatens to undermine access to certain medicines that Australians need and deserve. Medicines Australia will continue to argue that the cost recovery bill should be rejected.

The key question to be resolved here is: do the draft regulations remove the risk to access to certain medicines on the PBS? We contend that they do not. Quite simply, the regulations fail to remove the disincentives for a company to seek a PBS listing for a medicine or an expanded indication where the total costs for preparing the submission and submitting the application outweighed the benefits of listing for the company. More specifically, the regulations lack any detail on the criteria to be used in the determination of waivers to be applied to fees where this is in the 'public interest'. It is insufficient for detail to be placed merely within an explanatory statement. Second, the decision on whether a waiver is granted on public interest grounds will only be made subsequent to a lodgement of a submission. This means that information on a fee waiver will not be available at the point of time when a company is considering whether to direct resources into developing the submission. The disincentives introduced by the cost recovery arrangements have thus not been removed. The risk to access to medicines for small and underserved populations remains. Third, there are no provisions in the regulations to remove the disincentive for companies to seek to expand the eligibility criteria for access to a PBS listed medicine. Such evidence takes many years to collect, and the marginal benefit of seeking a listing diminishes as a medicine moves towards the end of its patent life. The proposed fees serve to exacerbate this existing feature of the system.

In short, the regulations do not provide the protection recommended by the Senate's earlier inquiry into the legislation. Given this, how can the Australian public, the elderly, the children, the families, be satisfied that this measure is in their interests? Why is it also not reasonable for Australian industry to conclude that the unseemly haste to boost government coffers is at its expense and motivated by something other than providing access to medicines? If they cannot guarantee greater access to medicines, then these regulations and the proposal generally are at best misguided and counterproductive.

I would also like to make another point on behalf of our member companies. Any attempt to defend this policy on the basis that the pharmaceutical industry can afford it is completely missing the point. It is a total irrelevancy. The pharmaceutical industry overall will not be overwhelmingly impacted financially by so-called cost recovery. We have never claimed it would. However, every additional impost must be weighed up in the upfront cost calculations that each company makes as to where it should best allocate its resources.

This debate is not about industry turnover or earnings. This is a debate about public policy and whether this is good public policy. It is about behavioural economics. It is about how policy determines the incentives that shape human behaviour. The bottom line here is that if you introduce a disincentive to seek a listing for a medicine, do not be surprised if that listing is delayed or not submitted. Thus, the only possible loser in this case is the Australian public.

For what is the government willing to risk undermining access to medicines that the Australian public need? A total of \$14 million per year. For this, it is willing to put at risk medicines for paediatrics, palliative and Aboriginal and Torres Strait Islander populations. For this, it is willing to put at risk access to certain cancer drugs. If access to certain medicines is put at risk, this current fee-for-submission proposal should not be supported. We commend our recommendations to the Senate committee.

**CHAIR**—Thank you. Dr Shaw or Mr Bruce, do either of you want to make a comment?

**Mr Bruce**—No.

**Dr Shaw**—No, thank you.

**Senator COLBECK**—I was going to ask you whether the release of the regulations have negated any of the concerns you expressed at the last hearing but, from your submission, I think that would be almost asking a rhetorical question.

**CHAIR**—I think that answer has been given.

**Senator COLBECK**—I do not think I need to ask you that; you pretty much covered that. In your submission you talked about the review rights and the department making a decision about a fee within 14 days. You suggested that there needs to be a substantial period prior to a submission being lodged. Can you expand on that for me?

**Mr Delaat**—From my own experience in working for a large pharmaceutical company, I know that companies will make decisions six or 12 months ahead of the actual submission. They will be making decisions about the complexity and costs involved in putting that submission together. With the addition of costs recovery fees, of course that is another up-front cost that companies will be weighing into the whole equation. It is too late for companies to have that decision about a waiver being made at the point of making the submission because, by then, you have already had those up-front costs so you are hardly going to incur those costs without any certainty that the product is going to be waived. That is the issue that we are making very strongly: it is really a bit of a nonsense to think that a company will even go all the way through to making a submission expecting that they will have a decision within 14 days, because they will make that decision six or 12 months beforehand. If there is no mechanism—and it is tough to see how that mechanism could even be put in place. I am not sure it is even workable, but it is tough to see how a mechanism could be put in place whereby companies could have a meaningful dialogue with the department about that particular submission so far in advance.

**Senator COLBECK**—I hope you heard the comments that were made by Palliative Care Australia earlier about a potential recommendation from one of the reference groups, which would in itself be a mechanism where that reference could be made, then the work could be done to put a submission together and that process occur. That would be one mechanism that could be inserted into the regulations that would provide for that level of notice that you are asking for rather than the process where you lodge an application and you wait for 14 days. I think also within the regulations it states you have to withdraw an application within 14 days to get your money back anyway. So, if you do not get your notice in time, those two time frames are a bit interesting too.

**Mr Delaat**—The getting the money back in 14 days if you withdraw does not help the other issue that I was explaining about—

**Senator COLBECK**—The cost of preparing the application.

**Mr Delaat**—The cost of preparing the whole application.

**Senator COLBECK**—In respect of the budgetary issues, obviously this came as somewhat of a surprise to the industry when it was announced in the budget, how many of your members would have allowances within their budgets for a starter and even a start-up of this process?

**Mr Delaat**—None to our knowledge—I say that generally. There was no recognition that these cost recovery fees would be put into the budget early this year. I am not aware of any of the major companies—I would say none of the companies at all that would have been anticipating this measure and, therefore, putting

these fees into their budgets for 2008. If they are on a calendar year budget or possibly even between July and June next year, that would have given them some heads-up having the announcement in May, but certainly, for calendar year 2008, they would have had no knowledge of that.

**Senator COLBECK**—Most companies would be, I suppose, somewhat like governments: they start preparing their budgets earlier in a calendar year, even if it was a financial year budget so they would need that level of notice in preparing their budgets for the commencement of a program.

**Mr Delaat**—That is correct.

**Senator COLBECK**—And given that it was supposed to start on 1 July, it would have had to have had some impact on the operations or on the propensity to lodge submissions if it was going to start that early and they did not have the money budgeted.

**Mr Delaat**—Absolutely. It caught the industry on the hop. It is not that we had not known about cost recovery in previous years but it had gone very quiet—in fact, we thought it had been shelved. Then when the surprise announcement came down in the budget it caught everybody on the hop.

**Senator COLBECK**—Have you had any discussions about a proposed start date? I know the legislation has been defeated once in the Senate so far, and obviously this hearing is part of a process to potentially bring it back again. But during the consultation that the department has said has occurred since our previous hearings—I think during August was the timeframe they were talking about—has there been any indication of a potential commencement date?

**Mr Delaat**—I would like to use this opportunity just to point out there has been no consultation. We have not had any consultation on the draft regulations and the explanatory notes with the department at all. I think similar to the earlier speaker when you asked a similar question. So we have not had the opportunity to talk about start dates or anything else for that matter.

**CHAIR**—Mr Delaat, did you get a letter saying ‘contact the department’ when you got the regulations?

**Mr Delaat**—I will have to defer to my colleagues. We got a letter with the regulations.

**CHAIR**—Did that letter include an offer to ‘if you have questions please contact the department’?

**Dr Shaw**—I think we got the same letter as the AMA.

**CHAIR**—It would be useful perhaps if we had that letter, because I think there was the option there. I understand what defines consultation, but for the record I think it has to be clear what correspondence was exchanged.

**Mr Delaat**—I think consultation obviously can have different meanings. If consultation means sending out the regulations, well yes, there was consultation. But in fact there was no other opportunity, no contact to engage with us in terms of a meaningful consultation on the regulations or explanatory notes.

**Senator COLBECK**—So what was the process? There are two sets of regulations, two incarnations: one that was made available publicly the day that our report was brought down, and then another set was released a week or so back.

**Mr Delaat**—Yes, 12 September.

**Senator COLBECK**—With the draft guidelines as well. What was the process by which you received the first incarnation?

**Mr Delaat**—I might ask Andrew to respond.

**Dr Shaw**—It was emailed to us on the 22nd, the day it was public.

**Mr Delaat**—That is 22 August.

**Dr Shaw**—And then the updated regulations and the explanatory statement—the first we saw the explanatory statement was 12 September, about a week ago.

**Mr Bruce**—At 4.22 on Friday afternoon.

**Senator COLBECK**—So you have not effectively been engaged; you have been provided with information although there may be a paragraph asking—

**Mr Bruce**—There was a paragraph in the initial letter inviting further discussions on the matter.

**Senator COLBECK**—That was on the 12th?

**Mr Bruce**—No, on the 22nd.

**Senator COLBECK**—So you have seen two versions of the regulations at this point in time. You have no sense of how complete these regulations might be or how many further incarnations down the track they might be likely to go?

**Mr Bruce**—In the second letter that we received, it was mentioned that we should not consider these to be the final set of regulations and that these may change in the future.

**Senator COLBECK**—There has obviously been no discussion regarding the progress of guidelines that inform the operation of the regulations?

**Mr Delaat**—Not at all, no.

**Senator COLBECK**—Just the draft explanatory notes. But my understanding from our last hearings was that there would be regulations and then there would be guidelines that would inform the operations of the regulations. Would you regard the explanatory notes to be an incarnation of those guidelines or you do not have that information?

**Mr Delaat**—We do not know quite how those came about. We received those on 12 September. That was the first opportunity we had—and, obviously, being an industry association representing a large number of members, we need to consult with our members in order to get their input and views on those regulations and explanatory notes. We really have not had a lot of time to have that consultation process internally. We have certainly not been engaged by the department to have that consultation—and we were very disappointed about that.

**Senator COLBECK**—Were you given any sense of the time you would have to peruse and comment on the guidelines when they first became available?

**Mr Bruce**—Only from the *Hansard* of the Senate debates, which suggested that we would have at least four weeks. But we assumed that would be a clean consultation period where we would be provided with a document and could work towards a date. At that particular stage we had a couple of processes running parallel. We had a Senate committee and we also had an invitation from the department to comment further.

**Senator COLBECK**—What would be your expectations of a genuine consultative process?

**Mr Delaat**—We have had a very positive experience with the department on other areas of policy development in the past. I personally co-chair the Access to Medicines Working Group with David Learmonth from the department. We have very good opportunities over the last year or so to work together. There has been good consultation on policy development in that area. So one would expect that there would be an approach to sit down and work through the regulations and the explanatory notes together—that we would be given an opportunity to provide that input. As Andrew has also commented, we have been working towards getting a response to this Senate committee review as well. So maybe we have been distracted from proactively going to the department ourselves. We have been working to get our comments back to this committee. But from our past experience we would have expected that they would have approached us in parallel to ask us for our views on the notes in the legislation.

**Senator COLBECK**—But, then again, part of this process is about us being able to satisfy ourselves that you are content with the consultation process, the iterative process, and possibly even the regulations, so that we can report that back to the Senate. In these circumstances, the legislation has already been presented to us. While it may be that you have been distracted by this committee process or that this has been the only opportunity that you have had to be involved in a two-way process rather than anything further, surely the fact that we are satisfied in our views as to your perspective would have to be an important part of the process.

**Mr Delaat**—I am sure it would. We can only reiterate that we were not happy with the so-called consultative process, particularly as the report from the department talks about consultation across a whole range of stakeholders, including Medicines Australia. If consultation is sending out that letter then we do not think that is particularly fruitful consultation.

**Senator COLBECK**—So, from your experience of consultation—with the department, you would have difficulty in calling this ‘consultation’?

**Mr Delaat**—Absolutely. We would have great difficulty in defining this as consultation

**Senator COLBECK**—You obviously do not believe the draft regs adequately address the concerns you have with respect to a cost recovery process?

**Mr Delaat**—Correct.

**Senator COLBECK**—Has there been any discussion with the department about a cost recovery impact statement, which is part of the guidelines for cost recovery?

**Mr Delaat**—Not that I am aware of. We have made that point on a couple of occasions—with our previous submission and now with the latest submission—but here has been no opportunity to discuss that with the department. We have obviously raised it in this forum before.

**Senator COLBECK**—If you go to the regulations themselves, what particular issues would you identify as key problems with the regulations as they currently stand?

**Mr Delaat**—As I said in my opening remarks, a couple of the key areas around the small patient population medicines, not only the initial listing of those medicines but also the expansion of listings on the PPS. I think that that is a piece that has been sort of forgotten in a number of the comments and discussions. A lot of the PBS listing that take place are actually for expansions of listings of existing products and often they are where the documentation and the evidence is being collected over time, over the period of the products life cycle, and sometimes they are for smaller patient populations. Oncology drugs are classic examples of where companies will concentrate on one area of cancer when they initially go to the PBAC for listing of the product. It may be for breast cancer, for example—and I think that there are real examples of this—and then within 12 to 18 months or two years they might expand that listing to prostate cancer, head and neck cancers and lung cancer. So companies will continually seek expansions of listings for products which in themselves are for relatively small patient populations. Therefore, we are weighing up the cost-benefit of expanding those indications.

**Senator COLBECK**—You mentioned oncology, which is another one that has not been specifically mentioned so much. So far we have done a lot of work through the committee on palliative care, Indigenous health and paediatrics but oncology is another area where there is room for adding to the indications that are listed on the PBS.

**Dr Shaw**—It is quite common for that to happen. Osteoporosis might be another area where you might have a range of treatments that the medicine is suitable for but only for one particular indication on the PBS initially. For example, patients over 70-years-old might have subsidised access to osteoporosis drugs, and subsequently a company might bring a submission forward to expand the listing to patients younger than 70-years-old. It is quite common across a number of therapeutic areas for that incremental improvement or expanded indication to occur. That is part of the development of the medicine and the collection of evidence going forward. It is not just in the palliative area or the Aboriginal and Torres Strait Islander area under paediatrics.

**Mr Bruce**—It is because they are the facts of the trial; it is not because a medicine does not work in this population. It is not because the medicine that is reimbursed for a 70-year-old does not work in the 68-year-old or 69-year-old. It is simply that the evidence available at the time of the listings is what can be established to be cost-effective, and then more trials are run and more data is collected and that data is submitted. That happens over time.

**Senator HUMPHRIES**—Sorry if you have answered some of these questions already while I was out of the room. You may have heard Mr Vines giving evidence earlier. He suggested that he could foresee a point reached in the future where pharmaceutical companies, which are international in nature, were able to synchronise or coordinate the preparation of applications for medicines so that there would be a negligible cost of simply repeating an application that had been done elsewhere in another country for approval under schemes like the PBS in this country. Is that a foreseeable and realistic vision of where we might get to in order to reduce the costs that pharmaceutical companies apparently have to meet in order to be able to make these applications?

**Dr Shaw**—To a point. One of the things with any sort of health technology assessment system is that it is quite dependent on the national circumstances. A country like Korea has quite a different cost-benefit system across its health system compared to a country like Australia or compared to a country like the US. National characteristics are quite important in the HTA system. The other thing, of course, is that if that were to occur, then Australia would be the only country in the world that we are aware of that would charge for submissions for reimbursement systems as opposed to regulatory systems. As we indicated earlier, there is no country that we found in the world that does what is being proposed.

**Senator HUMPHRIES**—Supposedly, other countries are prepared to go down this path, but, as you point out, none have actually done so at this time.

**Dr Shaw**—Not that we are aware of, no.

**Senator HUMPHRIES**—We are told that sometimes it is a marginal proposition for a company to apply not so much for the listing of a new drug but for the listing of a new application for an existing drug. Would you venture to tell the committee how many drug companies in this country have considered listing on the PBS but have not done so on the basis of the considerable costs associated with making an application, because they were low-volume drugs and therefore did not represent enough of a financial return to the company to make those applications worthwhile?

**Mr Delaat**—That is a pretty tough figure to try and think of. I think it would be tough for us to come up with a number, except to say that there are a number of times when companies will certainly weigh up whether a particular drug should be brought to Australia versus to other markets on the basis of incurring TGA costs, which we know are substantial, to get the drug registered in the first place and then the cost of the PBAC submission, which we talked about earlier. I cannot put a number on it. I would say it does happen. I personally have worked in a large multinational company where that happened and I know that that has happened in my own company from time to time. If you spread that across the whole industry, it would happen not irregularly—put it that way. And with cost recovery, and that is our whole issue here, that is a whole new burden, and one would have to weigh up those additional costs, in addition to the original ones.

**Senator HUMPHRIES**—Indeed.

**Mr Bruce**—Senator, if you look at the work of the Paediatric Medicines Advisory Group and the Palliative Care Medicines Working Group, you will see that they have actively targeted companies to list these drugs, and these are drugs that either there is not the data for or the companies have not seen that there is a cost benefit to bring it to the market at that point in time. So looking at those drug lists themselves that they have produced you can see that that is probably just the tip of the iceberg.

**Senator HUMPHRIES**—Okay. I asked earlier whether, if a drug's registration on the PBS was found to be in the public interest but the failure to grant a fee waiver would make bringing that drug to the market unviable, you should not in those circumstances require that the department must waive the fee rather than may waive the fee. Do you think it would be an improvement to the regulations if that change were made?

**Mr Delaat**—Knowing that we are opposed to the policy as it stands, if it were to be brought in then I think that would certainly strengthen the regulations. I do not know what my colleagues think about that, but I think it would certainly strengthen them. But all of this is designed to try and work around what is actually a very difficult policy to work around—whether it is actually workable in the context of companies having to make those decisions very early on. We were talking earlier on—I think you might have been out of the room—about the need for companies to make decisions about whether to put a submission together six or 12 months before the actual date of submission. Having one opportunity only to make the submission and having 14 days to find out whether you are going to get a waiver or not is really not going to happen in reality because companies are making that decision much earlier—and they may make the decision much earlier on that they are not even to go down that path.

**Senator HUMPHRIES**—In that vein, if I may, the regulation refers to an application being 'in the public interest'. I put it to another witness that surely all drugs that alleviate the condition of a person or persons in the community must be in the public interest, but the response to that was, 'Well, it may not necessarily be in the public interest to list the drug on the PBS.' Do you have a clear understanding, or think that members of your industry would have a clear understanding, of what 'in the public interest' meant in this context? Should it, perhaps, be better defined—or defined at all—in the regulations?

**Dr Shaw**—I think that, by definition, medicines that are listed on the PBS have to be evaluated by the PBAC as cost-effective, value for money or in the public interest, so there is already a review committee that makes an examination and says, 'Yes, having this medicine subsidised is in the public interest.' I am not aware of too many medicines subsidised under the PBS that are not in the public interest. The other thing is that the explanatory statement has a little bit more detail—there is no detail in the regulations around it—but, as I said before, we have only had about a week to look at the explanatory statement. But again, I think it does not address all the concerns we talked about before in terms of the access to different medications and so forth. By definition, if medicines are on the PBS then it is in the public interest to have them.

**Senator HUMPHRIES**—So what you are saying is that, in theory, every drug which is ultimately approved for listing is approved for listing because it is in the public interest, in effect.

**Dr Shaw**—They have all been recommended by the PBAC for listing.

**Mr Delaat**—I would also add in response to your question that certainly we would not be satisfied with the current explanation of what is in the public interest within the current regulations. It is very short on detail, and even the explanatory notes do not give clarity to that issue.

**Senator RYAN**—What struck me when I had a chance to look at these was regulation 10, which is about the independent review. My understanding of that is that the independent review cannot reverse or overrule a decision of the PBAC at all. Is that still true?

**Mr Delaat**—Correct.

**Senator RYAN**—I was wondering: given that I understand that it was meant to be independent of the PBAC, do you have a reason why this was included? Was this previously foreshadowed—did I just miss it?

**Mr Delaat**—I can only imagine that it was included because there should not be a disincentive to go for resubmission versus an independent review. It is the same with the timeline for an independent review; there is no advantage or disadvantage in either resubmitting or going for an independent review, because the timelines are exactly the same, so you cannot game the system in any way. I assume that that was similar in terms of cost recovery—the department did not want to waive the fees because it might send people down the route of going for independent review if they waived the fees, and they wanted, I presume, to make the fees the same. But, again, we find it very odd that you are even having to pay for an independent review in the first place.

**Senator RYAN**—Are they overseen and managed completely independently of the PBAC?

**Mr Delaat**—They are.

**Senator COLBECK**—I have one final question. I want to go back to your point with regard to getting a decent period of notice as to whether or not you might get a fee waiver and the impact on other elements of the business, particularly R&D, given that we have a green paper on innovation out at the moment. There was some discussion previously about the impact on R&D and investment given that you are having other costs applied to your businesses through the cost recovery. Do you still believe that there may potentially be an impact on innovation or R&D investment should this come as part of your costs, given that one of the other sides is cost pressure and that there is no opportunity—or limited opportunity—to recover your costs?

**Mr Delaat**—I think that where the intersection comes with the innovation agenda is that companies will make rational decisions about their resource allocations and that many companies, big and small, are undertaking clinical trials, other research projects and support for universities and education. So, to the degree that all of those areas are part of the innovation agenda, I think companies will end up making some rational decisions about resource allocation. If cost recovery is enacted then those additional costs will be a burden on the subsidiaries of those companies here in Australia, and they will be making decisions with their peers overseas as to where they should be spending their money. It may well be that other areas of their business will suffer because they are not able to support some of those other so-called innovative activities.

**Dr Shaw**—The other thing to bear in mind too is what was touched on earlier: the high number of resubmissions that are needed. If you are going to have a process like this, there needs to be some sort of commitment to reduce that resubmission rate. The average number of submissions that a medicine needs is two or three. Some medicines need a lot more. So we see the fees being \$120,000 per submission, but it might be quite a lot more for a lot of medicines if they have to come back again and again.

**Senator COLBECK**—Particularly in the instances of those indications for palliative care and Indigenous patients—the very small ones—if you decide to go ahead and do not get a fee waiver and then get knocked back, the likelihood of that going ahead would have to be questioned. That would be the circumstance where those issues would certainly come to pass?

**Mr Delaat**—That is right.

**Dr Shaw**—Particularly for smaller companies as well. There are obviously a range of sizes across the industry. For some of the smaller companies that operate in Australia that have only a couple of products on the PBS and have only three or four staff, those sorts of costs are quite substantial, particularly if their submission is knocked back the first time and they need to pay the fees again. It would add up. Again, as Will touched on before, that might tip the balance in the decision about whether to continue the submission.

**Senator COLBECK**—With the movement towards more specialised drugs that process could be further exacerbated, given you are talking about almost micropopulations. They are probably more likely to be in the realm of drugs that are going to need fairly significant information.

**Mr Delaat**—Correct. We have small member companies in the category that Brendan described. They have maybe a couple of products on the PBS here in Australia and a small number of employees. They produce medicines, vaccines and biologicals for small patient populations. That is their niche in the marketplace. They will be weighing up those costs: not only the initial cost of registration with the TGA but the additional costs of PBS submissions and potentially cost-recovery fees.

**Senator COLBECK**—So it is pretty difficult to say pharmaceutical companies get x hundred million dollars a year out of their interactions with the PBS and relate that directly back. There is no relationship. There is a cost in some circumstances to listing, given the cost-effectiveness test that is part of the overall process. I think \$300 million was ceded back to government by industry last year in the negotiations over the next 10 years. It was something of that order.

**Mr Delaat**—Some \$3 billion over 10 years was ceded back through PBS reform.

**Senator COLBECK**—So there has been a fairly significant iterative process between government and industry over the last year or two in respect of the costs of the PBS.

**Dr Shaw**—Arguably, those estimates could be underestimates as well in terms of the savings coming back to the government from PBS reform. The Pharmacy Guild have suggested that it might be \$6 billion because some of the government's estimates do not include some aspects of PBS reform.

**Senator COLBECK**—I am sure the industry is pleased to hear that. That is a fairly cheerful thing to finish on.

**CHAIR**—There being no further questions, thank you very much.

**Committee adjourned at 4.59 pm**