COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

Reference: Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009

WEDNESDAY, 8 JULY 2009

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SENATE COMMUNITY AFFAIRS

LEGISLATION COMMITTEE

Wednesday, 8 July 2009

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

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

Senators in attendance: Senators Boyce, Furner, Moore and Siewert

Terms of reference for the inquiry:

To inquire into and report on: Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009

WITNESSES

Committee met at 1.03 pm

MORROW, Dr Wendy, Executive Director, Complementary Healthcare Council of Australia

ROBERTS, Ms Kristy, Scientific and Technical Manager, Complementary Healthcare Council of Australia

CHAIR (Senator Moore)—The committee is going to consider the Therapeutic Goods Amendment (2009 Measures No. 2) Bill 2009. Welcome, Dr Morrow and Ms Roberts. Information on parliament privilege and the protection of witnesses is available to you. I am sure at least one of you has been before us before though. We have your submission—thank you very much. If either or both of you would like to make some opening comments you may and then we will go into questions. Would you like to make an opening statement?

Dr Morrow—Certainly. I will just say that it is the first time at a committee hearing for both of us.

CHAIR—It is going to be good; you will love it!

Dr Morrow—We were anticipating enjoying the experience.

CHAIR—Oh, good!

Dr Morrow—We are here today to speak on behalf of the complementary medicines industry and to represent our members. The Complementary Healthcare Council, the CHC, represents the entire complementary medicines sector, with our membership base consisting of health food store retailers and consumers through to raw material suppliers, sponsors and large and small manufacturing companies—all of whom have a focus on working within the complementary healthcare industry. The CHC is pleased that much of the work in relation to the Therapeutic Goods Act is starting to be progressed post the collapse of the planned joint regulatory scheme between Australia and New Zealand. However, we do feel that the progression of these amendments now should be consulted on within the context of an Australian-only environment.

Our first concern today is with the amendment to the advisory committee for medicine scheduling in regard to administration and constitution. The separation of the NDPSC into two separate committees—one dedicated to medicine scheduling and one to chemical scheduling—is not opposed by the CHC. However, we do not consider it appropriate that the TGA be responsible for administrating the separated advisory committee for chemical scheduling when its main role is to evaluate and monitor therapeutic goods. The CHC also raises questions as to whether it is appropriate for the TGA to be even responsible for evaluating chemical substances not intended for therapeutic use.

The TGA is a fully cost recovered agency. The costs are recovered through the therapeutic goods industry. We feel it is inappropriate for the complementary medicines sector in particular but also other therapeutic goods sectors to be subsidising an activity that is not related to therapeutic goods. We ask that an overview of the intended full cost recovery framework be developed before there is any further progression on this matter. The CHC questions whether the chemicals industry will be contributing to the running of this committee in regard to the secretariat, and we certainly do not believe that we should be paying for this.

Just for your information, the complementary medicines industry is about to receive an increase to its fees and charges of 14.3 per cent, which is a compromised value down from the 19.6 per cent required to break even. However, it is still a very significant increase for our industry, particularly given the current economic environment. Because of such an increase, we strongly disagree with having to pay for an activity that is not related to our industry in any way and which may consequently result in additional increases in following years.

The bill also lacks information as to how these advisory committees will be constituted. We do recognise that much of this detail will be included in the regulations; however, we would like to take this opportunity to state that there needs to be appropriate complementary medicine representation on the medicines scheduling committee. The CHC would also like to point out that the Galbally review concluded that the committee dedicated to medicine scheduling 'may benefit from an expert in complementary medicine', supporting our recommendation here today. It is imperative to have experts from the complementary medicines sector contributing to discussions and decisions relating to complementary medicine substances.

Our second concern is with the proposed amendment in regard to advertising offences. The CHC seeks further clarification about the proposed change to the inappropriate advertising of therapeutic goods. Currently, this provision only applies to sponsors; however, the proposal is to amend this so that any persons found to be advertising therapeutic goods inappropriately can be penalised. I should point out that advertising

reform has been flagged by the previous parliamentary secretary for health and ageing as an area requiring a comprehensive review. Industry supports this review and has been working on a whole-of-industry position to present to government. For these reasons, and on the understanding that, as the TGA has publicly stated, it is also well into its systematic appraisal of the advertising system, it would make more sense to simply hold off on progressing this particular amendment until the comprehensive review of the entire advertising framework is complete. It seems illogical to make piecemeal changes when a complete review is in the works.

The CHC strongly supports that advertising of complementary medicines should be truthful and for the purpose of informing and safeguarding consumers. We certainly recognise why this proposed amendment has been put forward and we can see that there is a benefit to this change. However, there is concern within the complementary medicine industry about how and when this provision will apply in certain circumstances. As an example, we note comments in a submission provided by the Department of Health and Ageing, from whom you will hear later today, referring to the fact that the ARTG publicly displays the approved purpose of the therapeutic good. The CHC would like to ask, whilst it is true that any person wanting to advertise a therapeutic good could and should look on the ARTG to discover the indications and claims, if the sponsor amended their entry during the life of the publication would the advertiser now be in breach? So the CHC requests clarification be given to the defence for an offence in this section of the bill. If the proposed wording remains as is, the CHC recommends that a defence be included either in the legislation or in guidelines to assist industry when an advertisement has been published in good faith. The CHC therefore asks the committee to recommend that a defence be developed to ensure legal certainty of enforcement application.

Finally, in regard to the proposed amendment to the legislative instrument for advisory statements, the CHC wants to ensure that the proposed provision to empower the minister to specify via a legislative instrument advisory statements for medicines will not mean that there is a change to the current consultative process with the complementary medicine sector. We are concerned that legislatively underpinning these advisory statements in a document, which we currently call the required advisory statements for medicine labels or RASML, will restrict or exclude industry from being able to input into this process.

This perception has been reinforced by comments made again in a submission provided to the Senate committee by the Department of Health and Ageing. They have noted that the statements within the RASML document will be transferred into a legislative instrument 'with minor changes that would have otherwise been made to the RASML document'. These sorts of statements are why the complementary medicine sector is wary of any future consultative processes being ongoing and is even more concerned about the transparency of the TGA. Obviously the CHC does not support a provision where consultation will be limited and requests that there be a recommendation that this legislative instrument be developed in full consultation with the complementary medicine sector. Again, we thank you for this opportunity and are happy to answer any question that you may have for us.

CHAIR—Thank you, Dr Morrow. Ms Roberts, do you want to add anything at this stage?

Ms Roberts—Not at this stage, no.

Senator BOYCE—I just wanted to spend a bit more time trying to understand the differences between the work that will be undertaken by the advisory committee on chemical scheduling and the advisory committee on medicine scheduling. I am hoping you might be able to give me an example of a substance. I know you mentioned products that might be used in paint or detergents, for example, but can you give me an example of how the chemical scheduling process would happen and why it is quite distinct from areas covered by your members.

Ms Roberts—The bill actually stated that they would be reviewing substances that were not intended for therapeutic goods compared to the medicine scheduling committee, which would actually be looking at substances for therapeutic goods. Obviously there would be circumstances where there could be an overlap between the two.

Senator BOYCE—So a product—

Ms Roberts—An essential oil or something like that would probably be—

Senator BOYCE—A mineral oil, did you say?

Ms Roberts—An essential oil—something like eucalyptus oil, which might be used in a detergent but perhaps also in a therapeutic good. We certainly do not oppose those two committees communicating and meeting when they need to. However, there is quite a difference between a therapeutic good purpose and not in the majority of what they would be looking at.

Senator BOYCE—Would you be able to give us an example, perhaps, of a substance that might be strictly in the chemical scheduling area?

Ms Roberts—And not intended for therapeutic—

Senator BOYCE—Yes. You have suggested to the committee the Office of Chemical Safety and Environmental Health. Would it already be doing some of the work that the advisory committee on chemical scheduling might undertake?

Dr Morrow—When they were considering medicines and poisons within the one committee, it was not an issue because within that one meeting they might have been considering both chemicals, such as bleach, which you would not ever use in a complementary medicine product, and a product such as sulfuric acid, which you may find in a homeopathic product. So while the two committees were together as one committee we did not have an issue as such with the administration by the Therapeutic Goods Administration, but the proposal now is to have two separate committees.

Senator BOYCE—Also, you were not being asked to pay for—

Dr Morrow—We were being asked to pay, but it was one committee.

Senator BOYCE—Yes—that statement had a query at the end.

Dr Morrow—We were being asked to pay for both functions—for poisons and for medicines—but because it was one committee they had to be practical. It would be very difficult to, say, split a percentage of the costs and give that to a different group within the Department of Health and Ageing.

Senator BOYCE—What are you paying now?

Ms Roberts—From what I understand, we are about to be paying for the evaluation under the new—

CHAIR—It says in your submission:

... a proposal for an increase to fees and charges for complementary medicines to be increased to 14.3% ...

Increased from what?

Ms Roberts—There is going to be an additional 14.3 per cent increase to fees and charges for complementary medicines as of next financial year.

Senator BOYCE—What are you paying now?

Dr Morrow—I am sorry; I understand the question now. We have a set rate for services that are provided by the Therapeutic Goods Administration. This year, for example, to list a product costs—

Ms Roberts—$560.

Dr Morrow—Thank you. Next year, it will cost 14.3 per cent extra for that service. We are not entirely aware as an industry whether we contribute to the secretariat for the NDPSC as it currently stands. However, the split has raised this question: are we going to be required to pay for chemical scheduling now separately to medicine scheduling? That is the issue that we have.

Senator BOYCE—But the fee that you pay now is in respect to the listing of a specific item. Is that correct?

Ms Roberts—That is right.

Dr Morrow—But that cost also covers post market review and—

Senator BOYCE—Some sort of administrative—

Ms Roberts—evaluation.

Dr Morrow—Yes. There are a number of other processes that we pay money for as an industry to the Therapeutic Goods Administration. It is not just for the listing of a product—that was an individual example. We are expected as an industry to pay fully for the costs that we incur by the TGA. To do that, we need a 19.6 per cent increase in fees and charges for this financial year. However, we 14.3 per cent was the compromise value, give that it is an economic recession.

Senator BOYCE—So 19.6 per cent is what they told you was needed for the TGA to break even on the activity. Is that right?

Dr Morrow—That is correct. That is what it would take for the complementary medicine industry to fully pay for that cost that the TGA is incurring.

Senator BOYCE—Do you have any sense of what percentage or volume of the work that is currently being undertaken by one committee would relate to chemical scheduling?

Dr Morrow—No. We currently do not have representation on the NDPSC. One of our issues has long been appropriate representation for the complementary medicine sector on government committees. This would be one of those committees. We do not currently have any—

Senator BOYCE—You would want to be represented on the advisory committee on medicine scheduling.

Dr Morrow—Medicines, yes, but not on chemicals.

Senator BOYCE—One of the other witnesses made the point that the terms 'chemicals' and 'poisons' seem to be used interchangeably, at least in the explanatory memorandum. Do you have any concerns about it being called chemicals scheduling rather than poisons?

Dr Morrow—As a pharmacist, I was always taught that a medicine can be a poison if you take too much of it or if you use it inappropriately.

Senator BOYCE—Anything can be; that is right.

Dr Morrow—Exactly. To me, if you are talking about a chemical it could also be a poison. I am not sure whether that answers your question.

Senator BOYCE—Yes. You do not have any concerns about—

Dr Morrow—No. Not from a complementary medicine point of view.

Senator BOYCE—what some submitters suggest might be a lack of distinction.

Dr Morrow—We would expect that a chemical would be something that is not intended for therapeutic use. That would be our understanding.

Senator SIEWERT—Following up on the issue around the chemical register, are you saying that you do not want representation on that committee. Is that what I heard you say?

Dr Morrow—For chemicals not intended for therapeutic use, no. The complementary medicines industry is a part of the therapeutic goods industry, and so therefore our concerns are in that particular sector.

Senator BOYCE—I want to talk about your concerns around advertising. I must admit that I understand a little better what you are talking about now. The advertisers who you are concerned about who might be inadvertently misrepresenting a product when they advertise it would be stores and the like—retailers. Is that what you are saying?

Dr Morrow—Errors made in good faith are our concern. I understand that good faith is very hard to define. Think of a magazine that is published for, say, three months, so the first version is out in January and the next version is out in April. If they have a sponsor on the ARTG, whether because of a section 31 notice requiring them to make the change or whether it is because of a change that they are making, what happens to the advertiser of that product in that time—for the life of that magazine—since the change has been made?

Senator BOYCE—So you are not talking about the magazine; you are talking about the person who has paid for the advertisement. Is that right? Or are you talking about both?

Dr Morrow—Both, because there are times when a sponsor pays to have an advertisement in a magazine, but there are also times when it is not the sponsor who initiates the advertisement but a distributor or a retailer. We fully accept that they have a duty to check with the ARTG—as proposed—to ensure that their claims and indications are appropriate. We are not suggesting that it is not the responsibility of both parties.

Senator BOYCE—You have also mentioned that there are a number of reviews of advertising going on at the moment. Is it correct that there are two reviews, with both the TGA and the department of health doing one? Or is TGA undertaking a review on behalf of the department?

Dr Morrow—It is my understanding that it—

Senator BOYCE—We can clarify this later today with the department. What do you think is going on at the moment?

Dr Morrow—It is our understanding that the TGA is undertaking a review of advertising. That is the only review that we are aware of. The complementary medicine sector is undertaking its own review of advertising. We have a common position with the TGA in regards to a number of the issues within advertising. It is a part of our sector that needs a lot of attention. Because it needs a comprehensive review, to pick little pieces off before you do a comprehensive review is not the best way to do it.

Senator BOYCE—So you do not think that anything should happen in terms of changing the requirements around advertising until these reviews are completed.

Dr Morrow—That is right.

Senator BOYCE—Can you tell me about the council's review? How long has it been going? What are you doing?

Dr Morrow—We were notified by Senator McLucas in late June or early July last year that there would be a comprehensive review of advertising. We took that on board. We have numerous meetings with the Therapeutic Goods Administration and we have for the last three months been consulting internally with our members and the complementary medicine sector to ensure that the industry has a good understanding of what the issues are, what needs to be changed and the type of system that we would to like to see in place so that we can put forward our recommendations to the TGA.

Senator BOYCE—When would you anticipate your review being finished?

Dr Morrow—Touch wood, our final meeting is later this afternoon. We are hoping to have the final draft for industry consultation by early next week. There are many slips between cups and lips, but that is what our hope is.

Senator BOYCE—So you would anticipate having a finished document that you can share with the TGA by the end of August?

Dr Morrow—Absolutely.

Senator BOYCE—What are some of the issues from the council's perspective? You said that it needs a lot of review.

Dr Morrow—It does. We do not maintain that the entire system needs to be removed and we need to start again. We believe that fundamentally the advertising system is appropriate. But there are issues in pre-approval of advertising. Do we need pre-approval? If we do, what form of pre-approval do we need?

Senator BOYCE—Is that not clear at the present time?

Dr Morrow—At the present time there are delegated authorities for preapproval. There are two delegated authorities and there is inconsistency in the decisions that are made between those two authorities. One of them is delegated authority to the CHC and the other is to ASMI. So there is—

Senator BOYCE—ASMIN being?

Dr Morrow—Australian Self Medication Industry.

CHAIR—The next witness.

Senator BOYCE—ASMI?

Dr Morrow—Yes, ASMI.

Senator BOYCE—Sorry. I thought you said 'ASMIN', and it was going to be a new acronym for me.

Dr Morrow—No. There is no-one new on the horizon that we are aware of. In the preapproval stage, there is room for inconsistency. Our concern is that, if you remove preapproval completely, there is no protection of consumers until the post-marketing phase, which means that the advertisements are already out on the market before they are reviewed. If that happens, it is like shutting the door after the horse has bolted. Interestingly, we actually find that in the system now that a lot of errors and a lot of issues with advertisements are not being picked up until the post-market phase. Industry is having a look at how we can work towards improving that part of the system.

When it comes to the complaints system, to my knowledge, there are three different authorities that deal with complaints. There is the CHC complaints committee, the Complaints Resolution Panel that is funded by the TGA—I am sorry, but you will need to clarify that perhaps with the TGA—and the ASMI complaints committee. There is a possibility of inconsistent decisions being made across those three delegated authorities for hearing complaints and so there is concern in industry that there are many areas that really do need review. We are talking about a review of an advertising system from preapproval to complaints to penalties and sanctions, which we have been advised could potentially rise significantly. Before they increase significantly and before small pieces of the advertising system are picked up on, we believe there needs to be a full-scale review of the advertising system.

Senator BOYCE—I have one last question. As you pointed out, this was part of quite a long process and, at some stage, it involved New Zealand looking at an Australasian process. Has anything been lost to the functioning of this legislation by the fact that New Zealand is no longer going to be involved?

Dr Morrow—Not to my knowledge. The regulations that were being discussed amongst Australia and New Zealand were separate to what is currently in place. So the Therapeutic Goods Act stands as is. A lot of the recommendations that are now coming forward arose out of that consultative process. Our concern is that we need to be sure that these have also been considered in an Australian-only environment as well as in an Australian-New Zealand environment, because New Zealand's regulatory system is very different from the Australian system. They are not as advanced in their regulatory system as we are in Australia, and they did struggle, I believe, with a number of components of what was being proposed. It would be reassuring, particularly in advertising because there are so many issues, to know that anything that is being put forward is in an Australia-only context because it appears unlikely that the Australia-New Zealand system will be up and running.

Senator BOYCE—I was thinking in terms of any members who might manufacture, sell, market or distribute into the two markets, which I imagine is quite a number of your members. Is there less certainty for them now about how they go about it?

Dr Morrow—I do not believe so, because the Australian system is still in place and it is still functioning.

Senator BOYCE—Thank you.

Senator SIEWERT—I have a couple of areas of questioning, but firstly I want to go to the advertising issue. I apologise for my ignorance, but do you have to seek preapproval, or does that depend on whether you want to cover yourself?

Dr Morrow—There is required preapproval for a number of types of advertisements—not all of them but a large percentage of them.

Senator SIEWERT—Is the decision on the preapproval compulsory in that you comply with the decision made by either organisation?

Dr Morrow—Correct. Currently, CHC has delegated authority for complementary medicine advertisements in print and ASMI has complementary medicines as well as others. But when it comes to complementary medicines in broadcast media, if it is a television ad, it will go through ASMI; if it is in a magazine, it will go through the CHC.

Senator SIEWERT—If the same type of ad is in both, who takes responsibility?

Dr Morrow—Both.

Senator SIEWERT—Secondly, in terms of the time lines that are taken to make decisions, are there requirements around that process as well? Would organisations be coming to us and saying: 'It takes a long time to get preapproval. We need it fixed' et cetera?

Dr Morrow—They may. It does depend on the clarity of what is being sought. So, if it is a simple advertisement that reflects exactly what is on the ARTG, you can have your approval in a very short time period. But if it is a more complex advertisement or if the advertising services manager, who is the person responsible for the preapproval, believes it to be a more complicated issue, they will definitely take a longer period of time. There might be some quite considerable provision of information by the sponsor to the advertising services manager to enable that person to make the decision and so it can take a long time. Yes, you may have people come to you.

Ms Roberts—I should point out that, during our consultation in developing, looking at and reviewing the advertising, that has not been one of the really big concerns from industry's perspective.

Senator SIEWERT—In your consultation process?

Ms Roberts—Yes. That particular issue has not been such a concern. I think people understand that, in certain circumstances, something might take a little bit longer due to there being requirement for a longer review or more evidence to be supplied. I would not say that it was a really major concern for industry from that perspective.

Senator SIEWERT—Essentially, you could describe what we are talking about as a system of self-regulation.

Dr Morrow—Co-regulatory.

Senator SIEWERT—If it needs changing—and you and the TGA are obviously going through that process—are people concerned that things have been slipping through? Have you got stats on how many that you have said no to or that have been amended et cetera?

Dr Morrow—There has not been a requirement to keep statistics in a meaningful sense. At the complaints end of the process there are some statistics. We do not believe, as an industry, that they are appropriate to allow industry to analyse for itself where the errors are occurring and how we could actually work on those areas to remedy them. The statistics that are provided are insufficient to give you a meaningful understanding of where the breaches are and what they are. It makes it very hard to educate industry if you do not know what the issues are that are being upheld.

Senator SIEWERT—Who do the complaints go to?

Dr Morrow—If they are below the line advertising, say, brochures and in-store advertising, they go to the CHC Complaints Resolution Committee. If they are above the line and mainstream advertising, they go to the complaints resolution panel. And there is also the ASMI complaints committee. They are the three, and who gets what depends on where it is advertised.

Senator SIEWERT—So it is quite a complicated process.

Dr Morrow—A very complicated process.

Senator SIEWERT—To streamline that would actually be a benefit?

Dr Morrow—It would.

Senator SIEWERT—In terms of your comments about the sponsor issue versus sponsor and the amendment as it stands in picking up everybody, what would you see as the most appropriate approach? Would it be to just go for the sponsor?

Dr Morrow—Not necessarily, because there are instances where it is inappropriate to penalise a sponsor for a breach that was caused by an advertiser without the knowledge of the sponsor. So we are not actually opposing the amendment itself. We do ask for clarification relating to a defence of an offence in this section of the act; however, what we are really saying is that this is one little part of the system that needs to be revised. That is really our issue. So our issue is not that you should not penalise the person who has committed the breach; it is just that we are concerned about the application of this section.

Senator SIEWERT—I am trying to think of a way forward if the committee thinks this is a significant issue. Because what you are recommending is that the bill not proceed, or that that bit is taken out, while the TGA review process is going on and while your review process is going on.

Dr Morrow—If we thought that there was a risk to consumer safety or an immediate risk to consumer health we would not hesitate for a minute to say, 'Yes, it should proceed.' However, this is an issue that has been long-standing. Review of the advertising system was actually flagged as a part of the Australian-New Zealand process. Unfortunately, at the end of a very long and protracted consultation process we came up with a system that nobody was happy with. I have been advised by the advertising unit of the TGA and I know that the industry is not particularly happy with it and I know that New Zealand is desperately unhappy with it. So at the end of the consultative period we ended up with a system that would not suit the two jurisdictions: Australia and New Zealand. This is not something that we have to fix immediately overnight and, therefore, we are asking that it be a part of the complete review.

Senator SIEWERT—So you would suggest taking that bit out and dealing with separately—and the other change you were talking about could potentially could be fixed in the bill with amendments—and letting the rest proceed.

Dr Morrow—Yes.

Ms Roberts—Correct.

Senator SIEWERT—I want to go back to an overarching issue. I have had people write to me saying that this bill misses the point, that it is going to threaten the complementary medicines sector and that they, broadly, are not happy with the changes at all. This is very different to what you are saying. You said that you support it in principle but there are some key areas that need fixing. Would that be an accurate analysis?

Dr Morrow—I do not know how specific those people have been in their correspondence with you, but I actually believe that a lot of the concern of industry comes from concerns about transparency and the application of the law. It does not come from the law itself, it comes from the fact of their thinking, 'If they do

this then they can do this to me.' So a lot of it is the fear of the unknown. That is one of the reasons for us suggesting that clarification be given in relation to a defence for an offence under this section of the act. A good example that I can give is that the ACCC has issued guidelines on country of origin and those guidelines are designed to minimise legal uncertainty for suppliers and sponsors. There have been a number of instances where a sponsor has been able to rely on those guidelines in their advertising response to a complaint. So I think you will find that if industry or parts of industry are writing to you saying that this is an absolute disaster, the answer is that it is because there is a concern about lack of transparency and application of the law.

Senator SIEWERT—So it is not the act itself; it is the interpretation of how it is applied that people are worried about.

Dr Morrow—That is correct.

Senator SIEWERT—I take you to the issue around the advisory statements. You said that you need more clarification around the legislative underpinning of the advisory requirements, which restrict this process from an industry prospective. Can you briefly take me through that and what you think would be the key things for fixing it.

Ms Roberts—At the moment the advisory statements go through a complementary medicines evaluation committee and then they are put out for consultation to broader industry. So industry still has a broader opportunity to provide input into what advisory statements go into the document we call 'RASML'. The concern that industry has at the moment with what they are proposing is that, in legislatively underpinning this document, will the consultative process still going to be there? Are we still going to have an opportunity to have input, because we believe that that is very important in any document, particularly in this one?

Senator SIEWERT—So your concern is that now that they are legislative instruments there will not be a consultation process?

Ms Roberts—Yes, a fair consultation.

Senator SIEWERT—So, basically, a clarification or commitment from government that there would be consultation—I will go into something else in a minute about legislative instruments—would fix that?

Ms Roberts—Early, fair and appropriate consultation and not just at the final stages when it is about to be implemented. That is what we are after.

Senator SIEWERT—Presumably, it will be a disallowable instrument and that is where the ultimate consultation will come in. But the point you are making is that it is not good to do it at the end of the process.

Ms Roberts—Yes.

Senator FURNER—I want to take you to your express view about inconsistency between committees in decisions on the advertising. If the medicines and chemicals advisory committees were not both supported by the secretariat in the TGA, would you not think that there might be a possibility of inconsistent decisions regarding the scheduling?

Ms Roberts—That is where there needs to be communication between the two. Obviously we want to make sure that you have the appropriate representation on each of those committees, but I think that where there could potentially be inconsistencies there needs to be good communication between the two committees where each is able to present their reasoning behind their decisions.

Senator FURNER—Proper dialog between the two committees?

Ms Roberts—Yes, definitely.

Senator FURNER—Do you think that there is an issue of having representation on both if there were proper dialog between the two committees?

Ms Roberts—From our perspective, as long as we have got representation on the medicine side, which is what is applicable to our industry, I would assume—and I am only assuming that the chemical industry would want the same sort of representation on their committee as well—that if those two committees can then represent why they have come up with their determinations you would, I think, come out with the right outcome.

CHAIR—Thank you for your evidence. Is there anything else you want to put on record?

Ms Roberts—Not at this stage.

Dr Morrow—No.

CHAIR—The transcript will be in *Hansard* in a couple of days. In regard to the question you have raised, we will be able to put those questions directly to the department, so we will be able to get responses.

[1.42 pm]

BROWNBILL, Mr George Metcalfe, Consultant, Australian Self Medication Industry Inc

SEIFERT, Ms Juliet, Executive Director, Australian Self Medication Industry Inc

CHAIR—Welcome. Mr Brownbill has given evidence to the committee before in another capacity. Ms Seifert, have you been before the committee before?

Ms Seifert—Yes, I have.

CHAIR—You therefore understand all about parliamentary privilege and protection of witnesses. Would you like to make opening statements?

Ms Seifert—You will all appreciate that this particular legislation is critically important to the non-prescription medicines industry, which includes over-the-counter medicines as well as complementary products, because it essentially regulates the way our members conduct their business in the marketplace. That in turn not only affects national health policy but has a direct relationship to it because an essential element in any reform is how you deal with access to safe and effective medicines with the very fewest appropriate restrictions on competition.

The scheduling system, which this bill deals with, provides for the rules about who can access medicines and what medicines they are able to access through which sorts of outlets. The rules allow for the classification of substances that go into those medicines. The safer these substances are deemed to be, the wider the access that is able to occur, and vice versa. So there is a very clear need to strike an appropriate balance here. We see that as one of the central issues.

Clearly, there is no such thing as any substance being 100 per cent safe, so what needs to be part of the system is a process that, in effect, includes and balances hazard assessment, risk assessment, a look at cost-benefit analysis and a degree of probability analysis, and all of those have to be appropriately linked. We are seeking that this bill ensure those processes are at the heart and centre of the scheduling system. We believe that in the past there has been an undue risk aversion and a lack of understanding of, in particular, consumer attitudes and marketplace behaviour. Also, particularly when it comes to the regulation of advertising of scheduled substances, an attitude has prevailed that our member companies or industry in general will pretty much stop at nothing to make a sale and that people lack the necessary degree of sophistication to understand what is actually being offered in a sale. That does, we believe, a great disservice both to our industry sector and to consumers in general.

I should say that ASMI, as we indicated in our submission, support the principles of the bill. In saying that, I would make the point that we want to cooperate with the government, through the TGA, and I acknowledge that there have been recent attempts to consult us, but we do not believe that they have been quite adequate. A 'take it or leave it' approach is not really the essence of good consultation. Similarly, not getting any feedback on what we believe are fairly carefully considered submissions over a period of going on 10 years now does not really constitute consultation.

We believe that this Senate committee will fairly quickly find that this bill is, in effect, little more than enabling legislation, so the question arises: what does it actually enable? Essentially, it assigns to some unknown and, in part, unaccountable officials powers to write legislation. That is actually parliament's job. Moreover, when parliament does delegate powers to the executive to make statutory instruments those instruments must be reviewed by the parliament and those who make them must do that in a very transparent way, making their reasons known. What we believe the committee will find in this bill is somewhat the reverse of that process. For example, the schedule is to be a non-disallowable instrument. Worse, the rules of law and policy about how substances are to be scheduled will not be a legislative instrument. They will be drawn up in what we would term a degree of secrecy by state and Commonwealth officials in no way accountable to any parliament.

We have proposed some amendments to the bill for this committee's consideration. They form appendix 4 to our submission. In general, we believe that the principles of good regulatory practice as laid down by COAG ought to apply. In our view, the government ought to have no difficulty with this proposition, as the whole scheduling scheme's authority derives from the Australian health ministers council, which is a creature of and which reports to COAG.

We will be happy to respond to any questions that the committee may have, and I might also mention, having heard the previous testimony of Dr Wendy Morrow, that I would be happy to pick up on any questions already asked in the area of advertising because, interestingly, the current advertising system actually had its origins in a very similar Senate committee of inquiry going back to 1989 when decisions about delegations and other aspects of the current system were made as a result of an inquiry. If it would be of any help to expand on any of that history and relate it to the current context, I would be more than happy to do that.

Senator SIEWERT—I am interested in your perspective on the thinking behind and issues around co-regulation of advertising, including what you think of the changes and whether you support what CHC suggested.

Ms Seifert—What I think of the changes being proposed?

Senator SIEWERT—Yes: proposed in the bill.

Ms Seifert—Let me start by saying that ASMI historically has worked within both the self-regulatory and co-regulatory arenas. The origins of the co-regulatory system go back to a situation which arose as a result of an attempt by the industry to self-regulate following the demise of the then Media Council of Australia. There were several codes that were administered by the media council that covered medicines, alcohol, dietary supplements et cetera, and when the media council fell over those codes were orphaned. ASMI at the time, together with the predecessor association to CHC, applied to the then Trade Practices Commission to take over the operation of that code. We were granted temporary authorisation pending the 21-day period in which anyone in the world could object, and somebody did. The case went to the tribunal and, during the tribunal hearing, one of the members of the bench posed the question of whether either association would have the power necessary to bring into line nonmembers of either of the associations.

Our understanding to that point had been that the Trade Practices Commission, in granting authorisation, would assist in dealing with non-member companies, so that there was in fact a level playing field established across all of industry. As it turned out, that was not the case. So ASMI and the then NFAA, the Nutritional Foods Association of Australia, went back to the Therapeutic Goods Administration and said, 'As much as we had hoped to continue to self-regulate, we now find we can't because we can't be a police force for our members alone; therefore you have to put things back into the regulations.' What we had in fact created as a structure that the Trade Practices Commission had liked became practically de-facto the regs—they were already in a form that could be adopted into regulation. So that was the birth of the co-regulatory system. We have worked with it and continued to support it and believe that it has served us well over the years. We have supported it within association by a self-regulatory code, which is a code authorised by the ACCC, which deals with complaints mechanisms for non-mainstream media offences, so that the two work in sync.

The bigger question—to address what you asked—is whether we have the right mix of effective consumer protection, appropriate levels of cost and appropriate levels of responsiveness to problems that arise in the marketplace. A review of that, I think, would be a good thing. I think there are a variety of models that could be put forward across the whole scheme, so I am not necessarily saying that we are in tightly wedded to what we have now. There are aspects of it that are difficult and pose problems. Some of those relate to other parts of the therapeutic goods regulations, so it is probably timely to review. We were not able to implement some of the ideas that came out of the trans-Tasman harmonisation efforts, simply because in that process there were what I personally would term huge concessions to the New Zealanders, who ran and have continued to run a similar but very different system based on similar principles but quite different application. What Australia has tried to do in all respects following the demise of trans-Tasman is to come to best Australian practice. In the advertising area, that probably has yet to happen and it will happen in due course when it is the next priority.

Senator SIEWERT—Do you support the comments made by CHC that that set of amendments in the bill be withdrawn and not dealt with until the industry consultation process has been completed, or would you rather see it dealt with now?

Ms Seifert—In an ideal world, perhaps, but I would not want to see that necessarily hold up the passage of this bill. I do not think it is crucial. We could live with it as it is at the moment. As part of a proper review of advertising, it may come up again to be looked at, but it should not hold up the passage of this work. I think some of the other issues that we have raised are perhaps more significant than that one to our sector.

Senator SIEWERT—You raised the issue of consultation both in your written submission and in your comments just now. From what I can gather from your comments, there was no consultation or little consultation before the bill was released.

Ms Seifert—It is true to say that, during the period of the work on trans-Tasman, there was extensive consultation. The problem we had was that, before the demise, we had had very little feedback on what we had proposed in submissions. There was consultation in terms of where the intent was to head going forward but not so much responding to why things we had suggested had been either dismissed or rejected. We pretty much feel that the same applies at the moment. We are trying to work in the context of best Australian regulatory practice. With some of the things that we have raised, particularly in the proposed amendments that we have attempted to draft, we think that consultation would have helped to iron out some of those issues and not impeded the progress of this bill.

Mr Brownbill—If I could add as a general point: what we have asked is that, considering that this whole process is a creature of a Commonwealth-state arrangement—the necessity for which under the Constitution we dispute in any event; but, since it is that—it ought to adhere in our submission to the very rules that the Council of Australian Governments have issued. For example, in the case of your question, Senator, consultation, I would refer you to the principles set out in appendix F of this document, which I can hand up later, the Council of Australian Government's *Best practice regulation: a guide for ministerial councils and national standard setting bodies*. I would refer you to, if I may, 'Appropriate timeliness'. It states:

... Consultation should start when policy objectives and options are being identified. Throughout the consultation process stakeholders should be given sufficient time to provide considered responses.

... Stakeholder groups should be informed of proposed consultation, and be provided with

information about proposals ...

Transparency—Ministerial Councils need to explain clearly the objectives ... the regulation policy framework within which consultations will take place and—

I emphasise this—

provide feedback on how they have taken consultation responses into consideration.

You will find at attachment 2 to our submission a list of all the submissions that my clients have made, and they have been all considered responses. The problem is that we have to make the same points each time because we find that the issues that we have put have never been taken up and have never been responded to in any considered way.

Senator SIEWERT—You have pointed out that there has not been adequate consultation on this bill—

Mr Brownbill—There has been consultation but it has not been meaningful.

Senator SIEWERT—I suppose that part of it revolves around 'meaningful', which you have discussed in relation to the COAG guidelines. Ms Siefert, you said earlier that you would not like to see the advertising process hold up the bill. I presume what you are saying now about the consultation process is that we make sure that we commit through the ongoing processes when developing the legislative instruments—those that are disallowable or not—that the principles being incorporated from now on into the process are only taken for the development of further policy under this piece of legislation.

Mr Brownbill—And what we say is that we have little faith to expect that to happen, unless the parliament so orders in terms.

Senator SIEWERT—I must admit that one would need to sit down with the bill and go through the detail of your amendments. You have quite a comprehensive list of amendments.

Mr Brownbill—Yes. They are drafting instructions.

Senator SIEWERT—Sorry, drafting instructions, but around amendments.

Mr Brownbill—Yes.

Senator SIEWERT—Thank you.

Senator FURNER—Just going back to consultation: are you able to detail what length of time was involved in the consultation concerning the recommendations of the Galbally review?

Mr Brownbill—I am not sure that I understand what you are asking.

Ms Seifert—The length of time of the consultation by Galbally.

Mr Brownbill—By her herself?

Senator FURNER—By the industry.

Mr Brownbill—I think Rhonda undertook extensive talks with industry. I know that, on behalf of my clients, I attended those talks at some length on several occasions. She conducted a painstaking and careful review and she made considered and appropriate recommendations. Subsequent to that, my clients made a submission to the government about what should be done about them. That was the start of a process, which is briefly referred to in attachment 2, where my clients would make a submission. There would be a long silence and then it would become apparent that the matters that we had proposed or requested information or advice on had simply been ignored. The government's position over those 10 years has remained unchanged until the circumstances of the trans-Tasman thing brought about a need for a turn of the kaleidoscope, so to speak.

CHAIR—Mr Brownbill and Ms Seifert, when you say 'ignored' is that ignored or not accepted?

Mr Brownbill—We do not know, because there is never any considered response. But it becomes apparent that they have not been taken up but not for any reason stated.

CHAIR—But does that necessarily mean ignored? I am just trying to find out. There was a process put in place. You have been engaged with the department over many years on these issues. It goes back a long time. You made a point both in your submission and in your evidence that you have not felt that it has been a satisfactory process. We are talking later to the department on this very point. When you say 'ignored' it may well be that it has been considered and not taken up, as opposed to ignored?

Mr Brownbill—It may well be. And, of course, when what is not on any record nor the subject of any communication, one cannot say which is the case.

CHAIR—I am interested in the language.

Senator FURNER—What is your position with respect to the legislation being in line with recommendation 7 of the Galbally review and also recommendation 5.1 of the Productivity Commission report on chemicals and plastics. Would you have a point of view on that at all?

Mr Brownbill—Are you referring to a separation of schedules?

Senator FURNER—Yes.

Mr Brownbill—We would support that.

Ms Seifert—Every submission we have made has supported that.

Mr Brownbill—Every submission for many years.

Senator BOYCE—I want to follow up on the question of consultation—meaningful or otherwise. In the summary of your submission, you state:

Industry does not accept that a take it or leave it approach amounts to meaningful consultation.

This issue seems to come up fairly often with the Department of Health and Ageing. What I want to tease out, if I can, is what the consultation involved? What actually happened with the consultation? Perhaps we might look at the last two years or so of the schedule you gave us.

Ms Seifert—It is certainly towards the end of the period of the work on the trans-Tasman. It consisted mainly of PowerPoint presentations that were a summary of ideas that had come up in submissions and a very brief dot-point overview of the direction.

Senator BOYCE—And the summary would come from—

Ms Seifert—From the consultants used by the Therapeutic Goods Administration. Sometimes they were internal people; sometimes they were people who were co-opted to do the work.

Senator BOYCE—Who would attend?

Ms Seifert—Industry.

Senator BOYCE—So it would have been a general invitation to industry—the same players all the time, so to speak?

Ms Seifert—Pretty much. My recollection is that most of the invitations came through the industry associations. There may have been direct invitations to companies, but they certainly went through industry associations as well.

Senator BOYCE—Are they held in every capital city, or—

Ms Seifert—In major cities, yes—at least Sydney and Melbourne. That is my recollection.

Senator BOYCE—When you put this together, it sounds like consultation. Can you explain for me why it was not meaningful consultation?

Ms Seifert—Meaningful consultation to us would be explanations of why certain things had been rejected out of hand and how decisions had been come to that did not appear to reflect the majority of the submissions that went in.

Senator BOYCE—So you would have seen a list, perhaps, of the ideas that had been put in by the majority of submitters as something that was going to be considered but then there was a vacuum?

Ms Seifert—I think there needs to be a robust process that includes a period of vigorous and robust debate about all the propositions that are put up. It remains the prerogative of the regulator and the government to put aside some of those proposals—

Senator BOYCE—Absolutely.

Ms Seifert—but it is only fair and reasonable that we understand the reasons behind dismissal or rejection and understand how they have come to the alternative proposals.

Senator BOYCE—Just following on from that point—I know you have said that this is basically good legislation but you have areas where you would like to see it improved—is there anything in this legislation that fits that criteria, which you were talking about, of something that is suggested by the majority of submitters but completely ignored or not taken up?

Ms Seifert—In general, the issues around accountability and transparency throughout the process have not been adequately addressed.

Senator BOYCE—So it is what is in the bill itself?

Ms Seifert—Yes. Different submissions have addressed it in different ways, but I think the broader principle of accountability and transparency is really the one that is not sufficiently represented and focused on in the bill being put forward.

Mr Brownbill—It is not by any means the first time that ASMI and others in industry have put points about the secret process run by a committee called the NCCGT, which issues guidelines which are then put into legislation as binding on the decision maker. Those guidelines have no input from industry, either before or after they are promulgated or proposed. If this legislation goes through as it is now, the parliament will have sanctioned that process of a non-accountable committee of officials meeting in secret and issuing rules that bind decision makers under the law, that are non-reviewable in any court or any tribunal and are not disallowable by the parliament. I am hoping the Senate finds those principles somewhat antiquated and wishes to do something about them. We have made that point in many, many submissions over several past years without success.

Senator BOYCE—As Senator Siewert pointed out, you have given us some drafting instructions, but, if what you have referred to as the policy framework is included in the legislation, would that primarily cover your concerns?

Mr Brownbill—The bill—and this is referred to in the document I referred to—says the secretary, in making the decision, must follow, must comply with, the guideline issued by this non-accountable body. We think that that body should follow some principles of transparency in reaching those rules and we think since it is a creature of the COAG it should follow the rules that the COAG has set down for all its subordinate agencies.

Senator BOYCE—Going back to your comment about guidelines having been made over many years in secret, what has the effect of that been on the industry?

Ms Seifert—It means that we have never really achieved harmonisation across all states and territories. Clearly that means not only inefficiencies but additional costs that, in the end, inevitably get passed on to consumers.

Senator BOYCE—Can you give me an example?

Ms Seifert—Differences in packaging requirements and labelling requirements—

Senator BOYCE—From state to state?

Ms Seifert—From state to state, as a result of decisions made in the scheduling arena. It is the same as the problem that we had between Australia and New Zealand. One of the things that Australia was at pains to try

and develop as part of that harmonisation program was a single market approach—having the same pack available in both countries. We have not in total achieved that in Australia. We have come pretty close, to be fair, but there are still occasional anomalies, and there is currently no way of ensuring that every state and territory picks up the decisions—

Senator BOYCE—There is nothing, in fact, to stop the anomalies getting worse.

Ms Seifert—Correct.

Mr Brownbill—And on an idiosyncratic basis—that is, some state may suddenly get a cranky view from some minister's constituent, a coroner's expression of concern or whatever it might be and the whole risk assessment process may go out the window.

Ms Seifert—If there is a legitimate reason within a specific state or territory for a difference then there should be a transparent process to clarify why that difference is necessary and whether it is a permanent one or it is a temporary one for an interim period after which it will be subject to review.

Senator BOYCE—Or perhaps, in fact, something that would be better picked up nationally so that consistency could prevail.

Ms Seifert—Yes.

Mr Brownbill—There should be an identification of the costs. The lack of conformity puts costs on industry because of different packaging, different marketing arrangements and so on, and that, of course, goes through to consumers.

Senator BOYCE—Yes. It is obviously not something that just affects this industry; I think it affects every Australian and makes us extremely inefficient in many areas. Let's hope sooner or later we can get it sorted. The other area I wanted to talk about was your comments regarding decisions that are very risk averse and the culture underlying those sorts of decisions. Are you saying that it is simply because of the states' structure or do you have other reasons for suggesting that?

Ms Seifert—I think it is the nature of the process as well as the structure. Clearly it is the perceived and the actual responsibility of the people around the scheduling committee to deal with consumer protection. There is no question that that is part of their mandate. However, that is not just a question of identifying a potential hazard at any point in time; it also means that they have to have the expertise at the table to move from hazard assessment to risk assessment—then there are issues of cost benefit and then there is the issue of how probable it is that this will occur. All of those things form a consecutive chain of analysis, and we do not see evidence of that chain of analysis forming part of the consideration and thinking within the current method and structure of that committee.

We would suggest that expertise is needed at the table and that it is lacking. Part of the reason that we addressed the potential for an independent chair is to perhaps bring some of those sorts of skills to the table. Our reason for putting that is not to say TGA does not have competence in this area; it is simply to say there are other skills that good governance would demand be part of the process. Just as I look at the committee of management for ASMI, while recognising that you want major players in the industry to be at the table, you select the actual players on the basis of the experience, expertise, skills and competencies that they can bring to a board. We are essentially putting up the same governance argument in relation to how this committee operates.

Mr Brownbill—It is not rocket science. Again, it is thoroughly traversed in the COAG document I averred to. In particular, appendix B deals with how you do risk analysis, appendix C deals with cost benefit studies and so on. We do not see any of that being applied.

Senator BOYCE—Both of you have used the phrase 'we don't see'—do you mean it is not apparent in the public information that is available or it is just not apparent full stop?

Mr Brownbill—There are extremely longwinded records of reasons published—extremely late, well after the decisions—which purport to record just about every word that is said. It is not apparent, from an analysis of those opinions, that many of the members go beyond hazard identification—they take a leap straight to action on a regulatory basis. I will give an example of a client I acted for some years ago. There was a question of whether a certain antibiotic could be added to a product that was agricultural feed. The question was whether it would create immunities and whether that would lead to premature deaths either of stock or of humans. My clients employed a very sophisticated hazard analysis, risk analysis and probability analysis mathematician from the United States, who came to the view that there would be no deaths, human or animal,

arising from this decision in 150,000 years, which seemed to me to be a reasonably acceptable risk horizon. That analysis was dismissed as irrelevant. I think industry deserves better attention to the processes which the COAG itself has laid down when these matters are under consideration.

Senator BOYCE—And, as you pointed out, those COAG documents have existed for some time.

Mr Brownbill—It is not rocket science.

Senator BOYCE—Are we talking about a culture here that is perhaps more relevant to other therapeutic goods analysis and is perhaps being misapplied?

Ms Seifert—I think there is an opportunity to improve process, and we are hoping that the Senate committee will help implement that change.

Mr Brownbill—We believe that if the processes in the bill and the processes in the subordinate instruments—if they are transparent and disallowable—are combined then the new processes will be a distinct improvement. We have some concerns, because we have no way of knowing what the makeup of the expert advisory committee or committees are going to be. We do not know if our recommendations about people who understand consumer behaviour have been accepted or rejected. We do not know because we have not seen the regulations—and nor has this committee seen them. So we do not know. But a combination of the processes in this bill—improved in the ways that hope the committee sees as justified—and a culture adjournamenta, let us say, might bring us forward.

Ms Seifert—While I appreciate your question about culture change, when we deal in the regulatory area I do not think that we can afford to rely on culture change as a solution. Having been in this position just on 20 years, I have learnt the bitter way that culture change takes a very long time. While I would love to be around to see it, I doubt that it is going to happen within my period of service with ASMI. It is really about appropriate process—and not only implementing but implementing it in a serious way monitoring it and evaluating it and having a transparent process for doing that. I see no reason why the COAG principles that we have referred to and other principles of good practice should not be able to be implemented in that way. The accountability lies in how you do the monitoring and evaluation. I see that as an appropriate function for the head of a regulatory agency, where ultimately the buck stops.

Senator BOYCE—I have questions in one small area. You made comments regarding a sponsor's holiday for people who successfully apply to list products that have a commercial-in-confidence period attached to them. How would you see that working?

Ms Seifert—You are talking about a period of exclusivity?

Senator BOYCE—Yes. What I am assuming is that you would get the chance to have a monopoly so to speak in the market—

Ms Seifert—A brief one.

Senator BOYCE—for a short period of time.

Ms Seifert—In return for having done the work that was necessary to put up the proposal in the first place.

Senator BOYCE—To sponsor the product and get it listed.

Ms Seifert—It is effectively to avoid the issue of piggybacking. When you have a substance based system as opposed to a product based one then inevitably someone does all the work and everyone in that particular substance area gets the benefit at the same time. That does not seem to be in anyway fair or reasonable. The commercial implications are quite significant.

Senator BOYCE—Obviously.

Ms Seifert—Most countries around the world with large regulatory agencies, such as the US and countries in Europe, have moved to do something in this area. We think that our request for a six- to 12-month period with those two proposed guidelines that are in our drafting instructions are really a more than fair and reasonable way of going about it.

Mr Brownbill—You will find similar provisions in the present Therapeutic Goods Act, section 25AAA—I think that is it; subject to check, but around there.

Senator BOYCE—I will take your word on that one, Mr Brownbill.

Mr Brownbill—I might have to be ashamed. But they deal with the protection of information and the protection of the position of makers of prescription medicines.

Senator BOYCE—But in most cases, as you have pointed out, they would not be a substance, would they?

Mr Brownbill—They are not a substance, no.

Senator BOYCE—That would be the distinction there.

Mr Brownbill—There will be a substance scheduled as part of the registration process, as is now proposed—and which we support—for prescription medicines. But we in the non-prescription industry sector think that we do not have not the protections or advantages of the prescription process, which leads to pharmaceutical benefit scheduling as well. Say there is a new substance—

Senator BOYCE—Or a new application for an existing substance.

Mr Brownbill—Or a new application or a new formulation. Whoever was responsible for that innovation should reap the rewards in a commercial sense for a brief period.

Senator BOYCE—But you are not necessarily talking about the inventor, are you, or the manufacturer?

Mr Brownbill—We are talking about the sponsor as that is defined in the Therapeutic Goods Act: the person who applies.

Senator BOYCE—In the Australian context, the sponsor would not necessarily always be the inventor or manufacturer.

Mr Brownbill—No. But they would have bought the know-how from somebody.

Senator BOYCE—They would have the Australian rights for something. Okay.

Mr Brownbill—It could be a product that was developed overseas and was sold under licence to an Australian sponsor. Equally, there is a company that I act for that is an innovator in a certain field of pharmaceutical goods and that have received grants for the development of products. If they do the work and they take the risk and, as it appears from these documents, they pay the fees—although we do not know what they will be—then it seems to us that the secretary, as the decision maker, should have a discretion to grant a period of no less than six months and no more than 12 months We have drafted this in the form of a discretion, not a right.

Senator BOYCE—What would that be based on? Where would you see the decisions lying around what constitutes the granting of six months as opposed to 12 months?

Mr Brownbill—As I recall, there were two criteria listed in the drafting instructions. They are on the second page. It is the proposed section 52EAA. It is subsection 8 of that proposed new section. It says: 'In exercising a power under subsection 7, the secretary may have regard to (a) the benefits to Australian industry that may accrue because of the encouragement a favourable decision may bring to innovative endeavour and/or (b) the nature of the outlays of time and money made by the application.' They seem to be fair and reasonable criteria for the decision maker to have regard to and not be bound by.

Senator BOYCE—I have one last question on the area of overlap or conflict with patents and trademarks law. Is that a consideration or a concern?

Ms Seifert—It should not arise.

Mr Brownbill—It should not arise.

CHAIR—Thank you very much.

[2.28 pm]

MARTIN, Mr Grant, Director, Professional Services, Pharmaceutical Society of Australia (witness sheet obtained)

SORIMACHI, Dr Kay, Director, Policy and Regulatory Affairs, Pharmaceutical Society of Australia (witness sheet obtained)

CHAIR—Good afternoon, Dr Sorimachi and Mr Martin, representatives from the Pharmaceutical Society of Australia. Have you given evidence to an inquiry before?

Dr Sorimachi—No.

Mr Martin—No.

CHAIR—This seems to be a chance for people to get their first go. It is very straightforward.

Information on parliamentary privilege, privacy and the protection of witnesses is available. We have your submission. Thank you very much. If either or both of you would like to make an opening statement we will then go to questions. It is up to you.

Mr Martin—I will lead off. On behalf of the society I would like to thank you for the opportunity to appear before the committee. I will give some advice on our submission with respect to the Therapeutic Goods Amendment Bill.

A bit of background on PSA. We are the peak national professional body for pharmacy. We represent some 75 per cent of the profession. We have a dual function in supporting pharmacists: commitment to high standards of patient care; and continuing professional education. We also represent pharmacists' role as front-line health professionals. PSA's primary role is to provide initial and on-going education, training, and practice support tools for pharmacists and pharmacy staff. We have been actively involved in the consultation process around the amendments to the schedules. We participated back in 2000 with the Galbally review. We were involved in the Australia New Zealand Therapeutic Products Authority consultations and we are currently involved in the TGA reforms to the Australian market.

We actively support the recommendation to split the schedules between medicines and poisons. We believe it promotes the safe and appropriate use of substances by consumers. I will pass over to Kay to give you an understanding of our submission.

Dr Sorimachi—In relation to our submission, we have restricted our comments to schedule 1 of the draft bill. Overall, we support the intentions of the bill. We have not commented on schedules 2 and 3 of the bill because they are a little bit outside of our remit at this point in time.

CHAIR—Sure.

Dr Sorimachi—With regard to the proposed amendments to schedule 1, I guess our comments could be regarded as seeking clarification. The first point relates to the use of the word 'chemicals', which appears to have appeared in the draft bill, which we had not previously been exposed to through either the existing act or the proposed new scheduling framework which was released by the TGA earlier this year for consultation. Whilst we do not particularly object to the word 'chemicals' we would like to know on what basis it has been used, given that the original recommendations arising from the Galbally review was focused around the word 'poisons'. We do see that the use of the words 'medicines' and 'poisons' as the two streams arising from this is consistent with what is currently in use now. As I said, both in the draft bill and the explanatory memorandum we could not see any rationale for the adoption of the word 'chemicals'.

So far as the second of our recommendations goes, it relates to subsection 52E(1). We have looked at the proposed new factors which are listed under the draft bill and we have looked at what exists in the current act and what was summarised as being proposed under the new scheduling framework. It is our view that three specific factors which are either currently in the act or proposed through the new scheduling framework are not explicitly listed in this draft bill. We have listed those in our submission, the first being safety of a substance; second, the patterns of use of a substance; and thirdly, the need for access to a substance. There is a clause in the proposed draft bill under this subsection (f) which says:

... any other matters that the Secretary considers necessary to protect public health.

We could argue that all of these could fit under that clause. However, we believe that these three factors are important enough to justify separate and specific listing under that subsection. I believe that is a summary of the points in our submission.

CHAIR—It was very direct.

Senator SIEWERT—I only have a few question, because you obviously only have a small number of issues. In terms of the replacement of the word 'poisons' with 'chemicals' you say—do you?—that the first time you knew about was when you saw the bill.

Dr Sorimachi—Yes, the bill, and it is used in the explanatory memorandum.

Senator SIEWERT—Yes, which goes with the bill.

Dr Sorimachi—Yes.

Senator SIEWERT—And you would prefer that it go back to 'poisons' so that it is quite clear what it is about. Is that so?

Dr Sorimachi—In terms of what is used now and if it is an ongoing measure, it would seem logical that you would retain those terms. It is not that we violently object to the use of the word 'chemicals'. But because there is no explanation as to why that term was chosen either we seek clarification or—

Senator SIEWERT—Obviously, we are going to be asking questions of the department shortly. So if we were to follow it up and there were an adequate explanation then you would be happy. Is that so?

Dr Sorimachi—We would consider the explanation.

Senator SIEWERT—Sorry, if there were an adequate explanation you would not then necessarily object to the use of the word 'chemicals' for that broader definition?

Dr Sorimachi—No.

Senator SIEWERT—I am wondering whether you have had a chance to look at some of the other submissions. I will ask that question firstly as it depends on what you say, which might negate any other questions that I have got around that.

Dr Sorimachi—We have not.

Senator SIEWERT—A number of organisations are suggesting some amendments. While supporting the legislation overall, they are suggesting some amendments around advertising, and I think you have heard some of the previous witnesses' comments. It would be interesting to know whether you support those amendments. It would be interesting to know if there is broad support for the amendments that are proposed by other organisations.

Dr Sorimachi—As we have not given due consideration to other submissions, we cannot comment on those. However, I guess it was our understanding that there are details which are not contained in the bill because they may be contained in subsequent regulations. We were going to reserve our comments until those were made available. However, we have made related comments through our submission to the TGA in connection with the proposed framework. Some of those revolve around the operation of the current National Drugs and Poisons Schedule Committee, which will be replaced by two committees. For example, we are particularly concerned about the timeliness of the announcement of outcomes of each NDPSC meeting. There is a very long time gap post meeting. In our view, that provides inadequate timelines for the profession to react to any changes to scheduling in terms of providing advice to pharmacists, to support their practice where it impacts on professional practice in a significant sense. Not all scheduling changes result in a significant practice change but some can. In those instances the PSA has a role to provide appropriate guidance and to provide any updates to existing professional guidelines. There is very little time to communicate that back to the grassroots level pharmacists. We are concerned about those kinds of issues. We did articulate all that in the separate submission but not here.

Senator SIEWERT—The reason I am asking if you have looked at the other submissions is this. Given that in principle you are supportive of the bill, I am wondering whether you would have any comments if there were amendments made along the lines of what has been suggested by the other organisations.

Mr Martin—It is quite possible once we have reviewed those recommendations. We would certainly have a look at that.

Senator SIEWERT—That would be appreciated. I would certainly be interested. Obviously, our job is to look at what people are suggesting around the bill, and people have been suggesting amendments. It then of course impacts on what other people think about the bill.

Dr Sorimachi—We can certainly get back to this committee on that.

Senator SIEWERT—That would be appreciated.

Senator FURNER—I refer to your concerns about 52E(1) and to the three matters that you have listed in your submission. If the intent is clear in 52E(1)(f) of those being captured to cover any matters that the secretary considers necessary, I take it you would not have an issue with that then applying.

Mr Martin—It is more that we believe these terms make the clause more explicit. There could be an implication. The secretary may well take that into account as part of the other power. But, by making it explicit and putting it down in black and white, we believe it creates a fuller picture when considering a product or a topic. We believe it is better to broaden the range, put down the full detail, in the first instance.

Dr Sorimachi—By grouping factors such as safety—which would be fundamental to making a scheduling decision—under 'any other matters' it does not justify, if you like, the importance of that factor in the decision-making process. That is why we have asked for a separate listing—to make it apparent that that is a key factor.

Mr Martin—You could argue safety if it is under toxicity, but we believe toxicity actually fits under safety—that is a better explanation—which is why we feel that the safety of the substance should be there in its own right.

CHAIR—Mr Martin, that was going to be my question—whether it did not fit under toxicity or under the risks and benefits. We will ask the department, as a threshold issue.

Senator BOYCE—You tell us that you represent about 75 per cent of pharmacists. What proportion of the over-the-counter medicines, complementary health products, that we are covering here would your members sell? What proportion of the Australian market would they represent, for instance?

Mr Martin—Selling through pharmacy?

Senator BOYCE—Yes.

Mr Martin—I am not sure of the exact percentage.

Dr Sorimachi—Perhaps we could answer it another way: 80 per cent of our membership work in the community pharmacy sector and all those would be exposed, in one way or another, to over-the-counter products.

Mr Martin—It would be a hard question to answer volume-wise, but it is about individual items. If you are talking about volume of product, obviously the OTC medicines that we deal with are also dealt with by supermarkets. If you are talking about product range, we would have a fairly large percentage of the market.

Senator BOYCE—You have said here that you have primarily reserved your concerns for looking at the regulations, the scheduling policy framework, when it comes out. We have had evidence already today suggesting that some people are concerned that that framework is going to be a disallowable instrument, not in the legislation itself. Does that concern your society?

Dr Sorimachi—We have not given any consideration to that.

Mr Martin—It is something we could consider from now, with that in mind. Up until now we have not considered it.

Senator BOYCE—Going back to your comment about the use of the word 'chemicals' rather than 'poison', other than the fact that there has not been a discussion around the change, do you have any other concerns about this change?

Dr Sorimachi—I guess there is not a concern per se. There are probably a number of terms that could be substituted for that.

Senator BOYCE—But what you are telling us is that if this were to be followed through with then we would end up with inconsistencies with other legislation and regulations. Is that correct?

Dr Sorimachi—It would appear so. If this is amending the existing legislation, perhaps all of that will be addressed. However, if you look at a separate document—the Therapeutic Goods Administration's proposed scheduling framework—which we commented on in May, as close to now as that was, that still contained the

word 'poison'. So it seemed a little bit strange that in this short period of time of a couple of months, this word has suddenly just appeared and we have not been exposed to it previously.

Senator BOYCE—I was looking at your suggestion that the bill does not require substances to be assessed under the safety of a substance, patterns of use of a substance and the need for access to a substance. Can you tell me why assessment of (b) and (c) are needed? I can understand the safety, but why do you need to assess (b) or (c)?

Mr Martin—Patterns of use can lead to the safety of a product—how the product is used by the individual, by the population. Patterns of use of medicine in an individual can link back to things like pseudoephedrine diversion. There is how the product is used in the market. Is the use increasing? Is the use decreasing? Is the use in a particular area? It relates to the overall use of the product. By reviewing the pattern of use we believe it gives a fuller picture of how the medicine is being used. 'Is it being used appropriately?' is probably the best question to answer. I might let Kay address the need for access.

Senator BOYCE—Can I just finish off on patterns of use. How are we going to have that data in many cases? These are not all cases where people have to give their names and addresses.

Mr Martin—In some cases you will not know, because there is no data collection beyond simple sales figures—wholesale figures and sales figures through pharmacies and through supermarkets. You will pick up some patterns there. But when you have got a prescription, for example—something where there is a name given—doctors are linked to that as well. You get a much better idea of the pattern of use and what is believed to be appropriate for the disease state it is being used for.

Dr Sorimachi—By saying 'patterns of use' you can capture both the appropriate use as well as misuse, and that can guide overall the context of how—

Senator BOYCE—Only where you have got names and addresses though.

Dr Sorimachi—The purchaser's identity might be a secondary issue. You might be gauging the pattern anonymously, but where there is a concern in the pattern of misuse, for example, that might lead to a proposal to change a schedule. So that is actually what has happened with pseudoephedrine-containing cold and flu products in Australia.

Senator BOYCE—I am trying to think of other products outside those that might be used for potentially illegal drug manufacture, where the pattern of use would be a concern other than if it were to be something that would cause health problems for the individual.

Dr Sorimachi—But it is not just about the misuse aspect. We need to have information about the trends of use of medicines that will guide future scheduling decisions on all sorts of medicines. We believe it is an important piece of information that should guide the scheduling decision-making process.

Senator BOYCE—For what purpose? I do not understand why, other than the fact that the industry will know they are selling a lot more of this.

Dr Sorimachi—In some instances the patterns of use may vary between jurisdictions. That may suggest that perhaps in one jurisdiction there is an increasing trend leading towards misuse and thereby that will trigger not only in the industry's mind but particularly in the pharmacist's mind that there is something happening at the grassroots level which warrants additional attention. Scheduling has in the past been used as a means to address issues of misuse. So we believe it does contribute—

Senator BOYCE—You are thinking in terms of products like pseudoephedrine, for instance, are you? I cannot think of any other sorts of areas where collecting that data might be worth the cost of doing so—that is all.

Mr Martin—The data collection is a fairly straightforward process. You are looking at wholesaler records. You could look at things like combination analgesics—are there sudden spikes of use in various areas? That could mean that they have worked out a way to split that product and misuse it from there.

Senator BOYCE—That is what I was trying to get to. Is that the sort of thing we are trying to ascertain by looking at this?

Mr Martin—Is there a new method for diverting products that we do not know about as yet? That might show up under this. The detail would have to be quite broad by the nature of what we are trying to check. Prescription medicines make it a lot easier, as do S3s that are recordable in some states. OTCs are harder to do.

But, still, broad trends in volume sales would be of interest. It is only part of the picture of what we are suggesting here. It would not stand alone.

Senator BOYCE—And why would we measure the need for or access to a substance?

Dr Sorimachi—One of the questions is that this need for access to a substance is a factor which is included in the proposed scheduling framework. So, the fact that it is not included in this amendment, we again are seeking clarification as to whether that is intended to be captured under any other matters or whether there is a reason for excluding that factor from the current list.

Senator BOYCE—It would seem to me that, in this particular area, the fact that someone wants to buy it demonstrates that there is a need. That would be the only requirement once you have met all the other safety requirements.

CHAIR—Throughout the process, you have indicated that you have been working with the department and so on. Before you end you evidence, is there any comment you want to put on record about the quality of consultation? Previous witnesses were saying that they had submitted ideas but were not getting formal feedback from the department. Has that been your experience?

Dr Sorimachi—We would agree with that.

CHAIR—In terms of the process, you cannot find a response to issues or an acknowledgment—that kind of thing?

Dr Sorimachi—It is somewhat ad hoc. In some instances, there is a time delay. Something appears to have been considered but, because we do not know the outcome, we do not know where it is at and then, suddenly, 18 months down the track the same or similar issue may arise. So, yes.

CHAIR—Are there any other comments that you wish to put on record.

Mr Martin—No, thank you.

CHAIR—Thank you very much.

Proceedings suspended from 2.52 pm to 3.18 pm

BROCK, Mr Craig, Policy and Public Affairs Director, ACCORD Australasia

CAPANNA, Mrs Bronwyn, Executive Director, ACCORD Australasia

CHAIR—Our next witnesses are from ACCORD Australasia, who provided an extraordinarily long submission. I am not quite sure whether all the senators have read it all! You have information on parliamentary privilege and the protection of witnesses. Would you like to make opening statements?

Mrs Capanna—In the interests of full disclosure I need to inform the committee that I am currently the appointed industry rep on the National Drugs and Poisons Schedule Committee. I was first appointed in that capacity in the early 1990s. However, today, I am presenting solely as ACCORD's executive director.

ACCORD welcomes this opportunity to address the Community Affairs Committee on the bill on behalf of the Australian formulated products industry. ACCORD represents the manufacturers and suppliers of consumer, cosmetic, hygiene and specialty chemicals products. You will be pleased to know that ACCORD is not an acronym!

Our submission outlines the many beneficial products our industry produces. These products range from luxury cosmetics to essential hygiene products right through to aerospace specialities. ACCORD's member companies are also responsible for more than 12,500 full-time-equivalent positions across the nation.

Our submission documents our industry's significant concerns with the bill and the arrangements it will put in place. These concerns fall into three main categories: firstly, policy concerns about the inappropriateness of placing chemicals scheduling into a non-chemical regulatory agency, the Therapeutic Goods Administration, both in terms of whether, one, this is legally valid and, two, the negative impacts of such a move on the COAG reform agenda for creating a more efficient nationally integrated system of chemicals regulation following the very detailed report the Productivity Commission released last year. Secondly, we have concerns about the overall lack of detail provided in the bill and the supporting explanatory memorandum. As a result, our submission raises 11 questions about the bill, which we hope the committee can assist with finding answers to. Thirdly, our submission documents the highly unsatisfactory nature of the agency-level consultation since 2005 on new scheduling arrangements. The chemicals industry is deeply sceptical that this will not improve should the bill be passed as written and things move to the next phase of consultation on regulations and possible cost recovery arrangements.

Our experience thus far is that the chemicals industry input on this important policy has been summarily disregarded and, unfortunately, we see no signs that this will change. Against all of this, our industry does not wish to be overly negative or obstructionist. We do not wish to block new initiatives that may, if seen more pragmatically as simply being interim arrangements, actually assist in progress along the path to the ultimate policy goal for chemicals regulation in Australia and for a more efficient, nationally integrated chemicals regulation system.

There are just too many unknowns arising from this bill for our industry to unequivocally say either we support it or we do not support it. In this spirit, our submission highlights the following: ACCORD has commissioned independent legal advice on the validity of placing chemicals scheduling in a non-chemicals regulatory agency, the Therapeutic Goods Administration. The short time frame for responding to and appearing before this committee means that this advice is still under preparation. With the committee's indulgence, ACCORD will table this advice once it has been received.

To a large extent, however, the recommendations contained in ACCORD's submissions are predicated on an assumption that the advice will not throw a major spanner in the works regarding the legal basis for the bill. On the basis that the bill's legal foundations are determined to be sound, ACCORD conditionally accepts what we understand to be the reason for using therapeutic goods legislation and the Therapeutic Goods Administration—that is, to avoid the need for new state and territory legislation, and that such new legislation would cause significant time delays.

If I could add a statement additional to our submission, it is a disappointment that in the long five years since the commencement of consultation on this important policy issue, no effort appears to have been made to develop a separate legislative model for chemicals scheduling. Surely, five years is ample time to have commenced such action.

The conditions on which our industry would accept the bill progressing, albeit reluctantly, are: that the arrangements be acknowledged as interim only; that there be a review in two years time to support a better and

more appropriate chemicals scheduling arrangement inline with the COAG chemicals regulatory reform agenda; and, that a proper consultation process be commenced with the chemicals industry in relation to the key details that will be in the regulations.

I have one final point, which is highlighted in our submission and is critical to this issue. Chemicals scheduling is an integral part of the very effective but overly complex and fragmented Australian system of chemicals regulation. ACCORD members predominantly manufacture and supply products for use in households. Chemicals scheduling sets essential safe-use instructions and storage warnings for those household products that contain more hazardous ingredients that require some degree of caution when used. Our industry strongly supports the role of scheduling in combination with other core elements of the overall chemicals regulatory system such as the requirements of the National Industrial Chemicals Notification and Assessment Scheme and the APVMA, but we believe industry, the community and governments would benefit from a better integrated system than the one which currently exists. The key problem is that the measures introduced through this bill place chemicals scheduling in the medicines agency, and therefore further away in both a policy and an administrative sense from NICNAS, the Office of Chemical Safety and Environmental Health, the APVMA, the soon-to-be established standing committee on chemicals and the proposed national environmental chemicals bureau. That is why we consider this to be a retrograde step. We would be very pleased to answer any questions.

CHAIR—Thank you. Mr Brock, do you have any statement at this time?

Mr Brock—Not at this time.

Senator BOYCE—Ms Capanna, you mentioned that ACCORD's suggestions had been summarily disregarded by the TGA and—presumably—by the government. We have had some discussion around the level of consultation and what constitutes meaningful consultation, and some witnesses have told us that their suggestions or submissions have been ignored. When you say your suggestions were 'disregarded', do you mean they were responded to negatively or not responded to?

Ms Capanna—Not responded to. We would reiterate the concerns that have been raised on the inadequacy of the consultation process and the feedback. Indeed, I go further. One of the questions that we have raised in our submission is about alternatives to the proposal as currently put forward in the bill—whether administrative arrangements could have more appropriately separated chemicals scheduling from medicine scheduling and whether they have been adequately investigated. We have been given, as other industry sectors have indicated, a one-only solution to a problem.

Mr Brock—To add to that, generally what we find when we deal with some other policy areas dealing with government—if you look at issues such as security-sensitive chemicals, for example—is that things work out much better if the industry and other stakeholders are much more engaged in terms of defining the problem and then suggesting solutions. We find that this consultation process, as it has operated since 2005, is at the very basic level of the agency providing information—

Senator BOYCE—About what their intentions are.

Mr Brock—about what their intentions are rather than engaging with industry and other groups to find out how we can best come to a set of arrangements that suit not just government but also industry and the community.

Senator BOYCE—Other than the major area you have raised about assessing chemicals within a medical framework, so to speak, what problems have arisen from that take-it-or-leave-it—as I think someone referred to it—approach to consultation?

Ms Capanna—We have proffered alternatives and either these have not been adequately investigated or, if they have, there has been no feedback. I think our greatest concern is that in this model you are submerging a key risk-management component of chemicals regulation in a therapeutic products regulator. The other distinction, of course, is that chemicals regulation is ingredient based and medicines are product based, so the systems are fundamentally different and the issues to be considered are fundamentally different.

Senator BOYCE—So you have the question of a substance versus a product, so to speak. One of our early submitters, the Complementary Healthcare Council, suggested that chemicals scheduling should sit within the Office of Chemical Safety and Environmental Health. In your view, is that a solution, and, if not, why not?

Ms Capanna—Yes, it would be a solution, because it would better integrate it with the overall chemical management and also keep it within the department of health.

Mr Brock—We still see that this is a public health issue and, therefore, it should be under the department of health. But we do not believe that putting it into a medicines agency is the best alternative. We cannot quite understand why the Office of Chemical Safety and Environmental Health, which exists within the department, has not been investigated as the house for this arrangement for chemicals scheduling.

Ms Capanna—And indeed they offer the current secretariat for the National Drugs and Poisons Schedule Committee, recognising that there are elements under the current system, which is joint medicines and chemicals scheduling. The office of chemical safety recognises that and deals with the Therapeutic Goods Administration, NICNAS as the industrial chemicals regulator and indeed the APVMA as the agvet regulator.

Mr Brock—Further, it deals with new and emerging issues. It would be looking at issues such as nanotechnology, which is a new issue coming up in the chemicals area; it will be looking at issues of security sensitive chemicals, and that is being run out of the Attorney-General's Department; and it will most likely interact with the environment agencies and the Environment Protection and Heritage Council proposal for a new environmental chemicals bureau. So there is a lot happening in chemicals regulation and, to put this key part of the chemical regulatory framework into the TGA, we think removes a possibility for greater integration and national coordination.

Ms Capanna—One of the key findings of the Productivity Commission was that the system was effective but was inefficient and fragmented—hence the desire to develop an integrated chemical control system and the development of a standing committee on chemicals, to recognise that there were elements of which scheduling is key to overall chemical control. This is why we are very concerned that the submersion in a medicines agency removes the visibility and also the validity of that component—people will not recognise it as the serious, significant risk-management component of the system because it is buried within a medicines system.

Mr Brock—This is significant because it is the part of the system that deals with the chemicals that the public use, the domestic use chemicals. It is very, very important. I think in our submission we highlighted a recent *choice* magazine article looking at cosmetic products and ingredients which failed to mention scheduling at all, and we find when we deal as an association with NGO groups that there is not a strong recognition that this scheduling system exists and that it looks at domestic use chemicals, sets storage and use pattern directions and does other things that are needed to ensure that there are not public risks out there.

Senator BOYCE—That was probably going to be my next question—the concern underlying all this is public risk?

Ms Capanna—Chemicals scheduling is the risk management component of the chemicals control system in Australia, particularly for the domestic chemical products. Controls over, for example, hair dyes, detergents and cleaning products, and consumer household goods are derived from chemicals scheduling.

Mr Brock—But we would have to add that the current system is effective, and that has been shown by the Productivity Commission conclusions as well in terms of dealing with those health concerns. We just think, again, burying it further within a medicines agency raises issues of whether that agency will be able to give adequate attention to these areas and how it will integrate with all of the other activities occurring around chemicals scheduling, because these things should be integrated, ideally.

Senator BOYCE—What about—and I am probably at the limit of my knowledge in this area—overlaps that can occur when products are used both as medicine and as substances, so to speak?

T **Ms Capanna**—In my view that is a furphy that has been promulgated to justify a singular committee for some time. Really, what chemicals and medicines scheduling is about is intended use. The committee would routinely specify the intended use: whether it is for a medicine or for chemical or household consumer use. This is clear in the current standard—the differential intended use. So the hazard of a chemical is not going to change regardless of its intended use, but its risk management—what concentrations you would allow as a cosmetic and what concentrations you would allow in therapeutic use—would change depending on the intended use. So it should be the intended use that drives this.

There is no need to keep the ingredients within the one committee or under the auspices of the Therapeutic Goods Administration just on the basis that there may be some ingredients that are common to both. Similarly, those ingredients that might be in therapeutic goods could also be in agricultural and veterinary products, and you would imagine that they would be treated quite differently because the regulatory systems are quite different.

Senator BOYCE—And presumably the expertise to assess their safety and efficacy in that particular use is quite different as well.

Ms Capanna—Precisely.

Senator BOYCE—Just going to the legal opinion that you are getting, can you explain to us—perhaps in some length—what you are seeking to find out?

Ms Capanna—The initial brief is to recognise that the National Drugs and Poisons Schedule Committee, as it is currently constituted under the Therapeutic Goods Act is a singular committee. Does the legal basis on which scheduling for chemicals can be undertaken by the Therapeutic Goods Administration and the Therapeutic Goods Act change when you separate the two committees? At the moment you have a committee under the Therapeutic Goods Act that does both. This bill seeks to separate the two committees, which we are supportive of in all of our submissions—

Senator BOYCE—But just not this way.

Ms Capanna—but just not this way. We are very concerned about the legitimacy of the chemical scheduling being done within a non-chemical regulator.

Mr Brock—There is a further issue to this, when you look at the intent, as we understand it, of the department or the agency to look at cost recovery measures. This goes down to how you apply fees and charges against the chemical industry introducers of chemical ingredients under the auspices of the Therapeutic Goods Act and the Therapeutic Goods Administration. It just raises a few of those questions as well. Not having seen the full detail of how the department would seek to implement these arrangements that are enabled by this bill, we find it very difficult to see how well that will be managed. We saw from earlier submissions and the witness testimony here, that that is an issue that some other industries have too: how will the cost-sharing occur under these new arrangements?

Senator BOYCE—We did have evidence this morning, I think, that the fees for a new listing would be $560, and that would increase by 14.3 per cent. Is that what you are talking about too, or is this a different schedule of fees that we are discussing.

Ms Capanna—This would be specifically in relation to chemical scheduling and the ingredient base for that. We have not seen any information on how the cost recovery process would be applied to the ingredient or the manufacturer or the importer. We have seen none of those details. I can understand the concerns that have been raised by other sectors—that you would not want to see cross-subsidisation between sectors.

CHAIR—How is it done now? How are fees handled now?

Ms Capanna—There are no fees for—

CHAIR—There are no fees in your industry because there are fees in the other part?

Mr Brock—No.

Ms Capanna—No; there are no fees for scheduling. Scheduling is generically ingredient based. There are service-level agreements, as I understand it, between the various agencies involved, but we have no transparency on what those costs currently are. So we have no understanding of the costs that would be imposed on our sector should this separation occur.

Mr Brock—That applies to the scheduling, but there are fees under the current system for the role of the National Industrial Chemicals Notification and Assessment Scheme.

CHAIR—And that is all scheduled—all those fees are listed?

Mr Brock—And that is all scheduled. That does the hazard assessment for the chemicals, which would then feed into this scheduling process where the scheduling committees look at the intended use and then work out what the risks are and what the controls should be around use, directions, storage and so on. There is already a cost recovery mechanism on our industry with regard to NICNAS requirements.

Senator BOYCE—We received evidence earlier from the self-medicating industry around giving sponsors of substances a short exclusivity in the market. What is ACCORD'S view on this?

Mrs Capanna—Chemical scheduling is a different control mechanism completely. It is ingredient based so it is not product based per se.

Senator BOYCE—I think we were actually talking substance based earlier. They were talking about things that would not be capable of being patented, obviously.

Mr Brock—In some way that is an area that we have not investigated with the membership of our industry. We would have to go back to them and seek some views from the companies as to whether that would be a

useful mechanism for them. I suppose, and I am speculating here, I would say that within our sector, the fast-moving consumer goods type sector, there is a high degree of competition within the sector as well so a measure like that may not be appropriate.

Senator BOYCE—So trademarks would be a more important protective mechanism within your sector?

Mr Brock—Yes, trademarks and brand recognition.

Senator BOYCE—I am just trying to work out how you would apply a measure like this in such a way that it fits one part of the industry but not the rest.

Mrs Capanna—I think that is another distinction between the two regulatory control mechanisms—that the Therapeutic Goods Act and medicines regulation is product orientated and the chemicals regulation is ingredient orientated.

Senator FURNER—Just on that subject, so you do not consider the pharmaceutical area as ingredients based; you consider it as something separate or chemical.

Mrs Capanna—The Therapeutic Goods Administration regulates the products primarily whereas the regulatory system in chemicals is predominantly ingredient based.

Mr Brock—With the exception of a APVMA, which is the agricultural and veterinary medicines sector, which is product based. It is a very complex system.

Senator BOYCE—Yes, and when do you have sufficient chemicals to call it a product?

Mrs Capanna—We have members who manufacture and distribute therapeutic goods. We have members who manufacture and distribute household and consumer goods. We have members who distribute and are controlled through the Australian Pesticides and Veterinary Medicines Authority. We have the privilege of being regulated by all agencies, and so we can see the differences, the pros and the cons if you like, between the different approaches. They are all predicated on risk management. That is why chemical scheduling for household and consumer goods is very important.

Senator BOYCE—My other questions related to some of the concerns that were released earlier around advertising and the changes proposed around advertising in good faith—and bringing in not just the sponsors of a product but anyone associated with the advertisement. Has that been an area of concern for your members?

Mrs Capanna—Because the key issue for our industry has been the chemical scheduling separation, we have not addressed those issues in relation to advertising and the other components of the bill.

Senator SIEWERT—We have covered all the questions I was going to ask.

Senator FURNER—Go to the issue of consultation, I understand that you might have been caught up in regard to the industry being involved in consultation through the recommendations of the Galbally review. Would that be the case?

Mrs Capanna—Yes, we were; but I would add that Galbally was last century and since that time we have had a Productivity Commission report specifically relating to the appropriate regulation of plastics and chemicals. Indeed plastics and chemicals regulation was identified as a hot spot of regulatory controls that needed to be solved. We have over 144 pieces of legislation pertaining to chemicals regulation alone—independent of business regulation et cetera. So you can understand the industry's desire to have a better integrated and less fragmented system.

Senator FURNER—Going to the Productivity Commission report on chemicals and plastics, it refers to a review, should the recommendations relate to the review undertaken by the AHMC, after two years operation of the legislation. Do you consider it appropriate for the Commonwealth to legislate directly for a review to be undertaken by the AHMC?

Mrs Capanna—Our support of this bill, should it pass, is conditional on the issues being an interim arrangement and that two-year review being undertaken.

Senator FURNER—So you do support the two-year review, basically?

Mrs Capanna—Absolutely.

Mr Brock—Just to add to that, we believe the two-year review should allow time for the development of a more appropriate set of measures to implement a better separation of chemicals scheduling. This can be done in the context of the work that is being undertaken at the moment through the COAG processes. We await the

government's establishment of the standing committee on chemicals, which we understood would provide a great deal of oversight on these types of issues. I suppose it is just a pity that the committee was not in place already because our recommendation would have then been to refer aspects of this bill to that committee so that it could determine how the bill would fit in in the context of the overall goals that the government has committed to following the Productivity Commission study last year.

Senator FURNER—What are you hoping to achieve out of the independent legal advice that you are seeking?

Mrs Capanna—I think it would set aside once and for all whether there is a legal basis or a legal concern in relation to having chemical scheduling within the Therapeutic Goods Administration.

Mr Brock—We also want certainty. If we do not undertake this review now and obtain that type of advice—and if this bill goes through as written and we find down the track that there is a challenge, which there could be, by an individual company or some party and then it is shown that chemical scheduling could not be put in the TGA's orbit—then we might have a problem that everyone is facing, which we do not want to have. We do not want that uncertainty for business and we certainly do not want it for the government either.

Senator BOYCE—I have a few questions on a little section that I neglected to ask previously. You point out that you have discussed your concerns and that you were told that the legislative approach being adopted was preferred because it avoids the need for new state and territory legislation. We have already had evidence from a number of people suggesting that uniformity between states and territories is improved but by no means consistent. Is that your experience and can you tell me a bit more about why you do not think this will assist in that area?

Mrs Capanna—I think it is important that you look at the examples of inconsistency now in relation to chemicals scheduling. This is linked to the individual schedules. For example, storage and handling in retail of S5 and S6 schedules—those are two different types of category—in almost all states and territories is dealt with definitely.

Senator BOYCE—So every state does it differently?

Mrs Capanna—There is a range from no legislation through to the most onerous legislation.

Senator BOYCE—This is methylated spirits and the like, isn't it?

Mrs Capanna—Yes. There are a range of requirements at a state and territory level that are linked to whether or not a substance is in schedule 5 or schedule 6—and similarly in the area of storage and licensing there are differences between states and territories. The reason why we wanted a separate chemicals scheduling committee was so that we could have the appropriate expertise and focus around what is the appropriate level of risk management for these and then apply that nationally.

Senator BOYCE—Good luck.

CHAIR—Have you read the department's submission?

Mrs Capanna—We availed ourselves of it very quickly but I could not say I was across all of the issues.

CHAIR—It would be very useful, because we will be asking the department questions later. In their submission the department have put a schedule of the consultation processes that have happened. It would be useful to get your view of how that has worked.

Mrs Capanna—In our submission we raised our concerns about the inadequacy of the consultation process—

CHAIR—You have.

Mrs Capanna—and I think it is fair to say that the consultation process and the details of the proposed system have focused, certainly from 2005, on the joint agency. The joint therapeutic goods agency was medicines; it was not chemicals. Indeed, chemicals scheduling was identified as an Australian-only practice. Our understanding was that, in the lead-up to the joint agency, separate legislation was being considered for chemicals scheduling. When the joint agency fell over—I think that is the acceptable term—AHMAC seemingly had a model in 2007. We have not seen that model from 2007. We have only seen detail around chemicals scheduling, to any great extent, in the most recent consultation, in 2009, and then after the bill was submitted. I suspect this is what we would regard as not meaningful consultation.

Mr Brock—With any of these processes, when we and other industry groups go to the effort of making a detailed submission—and in all reality you have to accept that not everything you propose will be accepted

and recommended—it would be ideal if agencies did what the government does when it receives a major report from a group like the Productivity Commission: it puts out a response and it goes through item by item saying, 'This particular recommendation the government supports; this one we do not and here are the reasons.' Once we see the reasons for a lot of these things we will often go back and start to think, 'That might be acceptable. There might be another alternative we can propose.' Out of that type of approach, as we have experienced in other policy areas, working collaboratively, we can generally come up with a better model with some industry input, not the sort of thing where you just have something imposed on industry and then you have carping and concerns expressed after the fact. We think that maybe an approach where these processes have a firm set of responses from the agency, ticking off or crossing out individual suggestions, would be greatly helpful to everyone.

Senator BOYCE—Would you say that in general there was a good understanding of industry practices and the reasons for them within the TGA and the AHMAC process?

Mrs Capanna—I think one of the difficulties for a medicines agency would be to keep abreast of all of the developments in chemicals regulation and policy, particularly as a consequence of the Productivity Commission recommendations. It would be extremely difficult for the medicines agency to maintain policy oversight and even keep up to date on those developments. There have been a lot of reviews in relation to chemicals and plastics.

Mr Brock—That is a public interest question for the parliament and for the government: can a medicines agency keep up to date with those things? The other thing is that the medicines agency's major role is regulating medicines and the safety of those; therefore is it a sensible approach for that agency to have other activities placed within it that are not within its main remit?

CHAIR—On pages 6 and 7 of the department's statement they talk specifically about the idea of having two separate committees, which has been a large part of your evidence. The department say:

(The states and territories have made it clear through the NCCTG that the single scheduling standard must be retained to allow appropriate reference in their respective legislation). ACCORD has been advised of this a number of times in meetings with the TGA and in related correspondence.

Mrs Capanna—Senator, if I may, just because—

CHAIR—You can disagree with me.

Mrs Capanna—No, just because we have been advised it does not mean to say that the rationale behind that has been clear or well articulated. As I have said, scheduling of chemicals and of medicines is intended use and that then feeds into the appropriate regulatory system. We would like to think that there could have been some further exploration, and indeed that is one of the issues that we have raised in our questions—the administrative arrangements that could have dealt with this better.

CHAIR—I take it the 11 questions are in part 3 of your submission?

Mrs Capanna—Yes. It is under part 3, 'Key questions related to the bill'.

CHAIR—Have you submitted those 11 questions to the department in that format?

Mrs Capanna—No. These are in direct response to the bill as presented and the explanatory memorandum.

CHAIR—So when was the bill presented?

Mrs Capanna—Two weeks ago.

CHAIR—Have you not contacted the department?

Mrs Capanna—No. While we recognised that there was a legislative time frame specified originally, we were optimistic that our submissions that raised detailed comment on the consultation documents would be taken into consideration, but that closed at the end of May and then the bill was presented.

CHAIR—In terms of specific questions to the department, the process about the separate schedule seems to be very important. You have received a response, but you do not believe that has been effectively explained.

Mrs Capanna—We have not received a response to our direct consultation and comments on the consultation documents that went out in April 2009. We have not received a response to that. As a consequence we were somewhat surprised that that time frame was adhered to. I suppose we consider it very disappointing that a Senate committee therefore is left to sort out some of these key issues that should have been dealt with in an appropriate, meaningful consultation system.

CHAIR—And the 11 questions that you have put in your submission and in your evidence—you have said they are the outstanding questions that you have.

Mrs Capanna—These are the ones in relation to the bill. We have further issues that we have raised in our consultation documents that we submitted at the end of May.

CHAIR—And you have received nothing back about those, but these particular questions you have not given to the department yet.

Mr Brock—No, not yet.

CHAIR—So you are using the Senate committee to get that across. Fair enough. We will put that through to the department. There will not be a chance for them to respond to all of these today, of course, but we will put these through as questions on notice.

Mr Brock—Ideally in this process, if there had been an exposure draft of this bill, we would have been able to put these to the department rather than through this committee.

CHAIR—That is fine. The committee has been used a number of times in that way, to actually be the point on which discussion around a particular bill can be had. So it is not unusual per se. I just wanted to be absolutely clear, because there have been a number of issues raised. The department has put through some answers in their submission but these particular questions relate to the bill as is. There are still ongoing issues about the relationship and how it will all work, but these are the specific questions. We will put that to them.

Mrs Capanna—With the committee's indulgence, is it appropriate that we review that and provide additional feedback subsequent to the witness statements of the Therapeutic Goods Administration?

CHAIR—Review their submission?

Mrs Capanna—Yes, their submission.

CHAIR—Yes, that is the idea. Unfortunately, we have been faced with a stream of tight time frames, but in terms of process the idea is that these submissions are all public. People can read reach other's submissions and then come to some further questions. I think Senator Siewert has already asked one of the previous witnesses to have a look at them as well. I know it is an awfully tight time frame, but having a very public process out there on the web is one way of doing it. On that basis, is there anything else you would like us to know at this stage?

Mrs Capanna—No. Thank you very much for the opportunity.

[4.00 pm]

MASKELL-KNIGHT, Mr Charles Andrew, Principal Adviser, Regulatory Reform, Therapeutic Goods Administration, Department of Health and Ageing

O'CONNOR, Mr Michael Peter, Director, Regulatory Reform Section, Therapeutic Goods Administration, Department of Health and Ageing

CHAIR—Welcome. You are very well skilled in the process of talking with Senate committees. As departmental officers, 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. We have your submission—thank you very much. You have heard many of the questions that have been put by various people today as well as their submissions. If you would like to make any opening comments, that would be welcome. If not, we will go to questions. I would expect that we would have questions based on the kinds of things you have already heard, so I doubt whether there will be any surprises. Mr Maskell-Night, do you have an opening statement?

Mr Maskell-Knight—I do. I thought it would be helpful. First of all, I would like to thank the committee for the opportunity to appear. I was going to outline what the main purpose of the legislation was, but that seems to have been well and truly done by everyone else from the tenor of the questions. I thought it was probably worthwhile saying that the main objective is to put a framework into the act to support the implementation of recommendation 7 of the Galbally review, which was actually in 2001 and not last century as someone said a moment ago. What Galbally recommended was an amendment to the act to disband the national drugs and poison scheduling committee and establish two committees—one for human medicines and one for other chemicals—with decisions on both categories of substance to be included in the one document to the one standard. The Galbally review also recommended the act be amended to add a cost to be recovered from the ministry. That is precisely what schedule 1 of the bill does.

As you said, we have been here all afternoon. There are were a number of statements and ideas put forward which I would like to address. I am sure your questions will allow me to do that. Perhaps at the start though I should say that there seems to be a misconception that because something is in the Therapeutic Goods Act it means the Therapeutic Goods Administration is going to be solely responsible for it. That is not so. The act confers power on the secretary of the department; the Therapeutic Goods Administration is a division within the department. We are the secretary's arms and legs in relation to medicines. The proposal is not that we suddenly become the secretary's arms and legs in relation to chemicals. The idea is that the Office of Chemical Safety and Environmental Health will continue to support the secretary in that role. The secretary can delegate their scheduling decision-making powers to any officer within the department. The expectation is the medicine scheduling power will be devolved to the TGA and the chemical scheduling power will be devolved to the office of chemical safety. The intention is to have a common secretariat for the advisory committees within the TGA. The reason for that is to facilitate exchange of information between the two committees and also, frankly, it will be cheaper for the industry if we have one committee rather than two.

The other issue I think is worth addressing at the start is the legal validity issue. First of all, chemical scheduling already takes place under the Therapeutic Goods Act. The act sets out as one of its objectives in paragraph 4(1)(b) is:

- (b) to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.

It then defines a poison as including anything in the poison standard. On that point, I should also say that during the drafting of schedule 1 a number of issues emerged where we sought advice from the Australian Government Solicitor and they did not raise any qualms at all about the legal validity of what we were proposing. The Australian Government Solicitor are not shy about pointing out where they think things are not going to work and they did not have any qualms whatsoever.

I guess the third matter is that the Australian Government Solicitor also observed that having two separate pieces of legislation amending the one poisons standard would raise a whole lot of interesting and novel legal issues and that they did not think that was a very helpful way to proceed. I will not detain the committee any longer. I am happy answer any questions.

CHAIR—I was going to start with Senator Boyce but as she is no longer here that is obviously not going to happen. We have some questions that were asked by previous witnesses.

Senator SIEWERT—Maybe we could start with those.

CHAIR—That is probably the best way to knock it off, Mr Maskell-Knight—to focus on some of the things that were raised earlier. It would be fair to say that we want to talk with you in depth about the consultation process. Rachel, is it okay if we lead off with that?

Senator SIEWERT—Yes.

CHAIR—You have heard the comments. One of the issues is that the process has been going for a long time. Mr Galbally brought out the report, it got lots of focus at the time, we were looking at having a cooperative arrangement with New Zealand, and all kinds of things happened. It seems to have been hanging around for a long time. A number of the witnesses have said, both in their written submissions and in their evidence today, that they felt unsatisfied with the process of consultation, not just because of the result—though they have raised particular questions about what they would have preferred to see—but because they felt they were not getting a response. They would bring forward ideas, put forward issues and they would go into a black hole. I am paraphrasing a bit—and I am sure my colleagues will jump on me if I get it wrong—but the idea was that there was no interchange of ideas. On a number of occasions today people identified quite specific examples where recommendations had not been acknowledged, where there was not explanation as to why they could not be taken up or where there was not even some kind of discourse about the value of them. It would be useful if we could hear your response.

Mr Maskell-Knight—There essentially have been three major phases of consultation that the TGA has carried out. The first one was in 2005. We undertook consultation in August and September. If you look on the TGA website you will find a document of 15 December 2005 which sets out what the response to that consultation was. It has been said that we do not respond; well, we did put a document up on the website that says, 'These are the observations that were made and this is the response.'

CHAIR—That was 'stakeholder consultation on the proposed scheduling models, August-September 2005'?

Mr Maskell-Knight—Yes.

CHAIR—And then the document—

Mr Maskell-Knight—On 15 December a document that summarised all that was put on our website. I concede it was just before Christmas. On the other hand, it has been there for 3½ years now, so people should have been able to catch up with it.

The second phase was in the lead-up to ANZTPA. There was not an outcome summary or feedback loop put in there, and the reason for that was that ANZTPA—I forget what the various locutions were—did not proceed—

CHAIR—as the end result.

Mr Maskell-Knight—Yes.

CHAIR—That was Auckland and Sydney, 8 and 13 November 2006?

Mr Maskell-Knight—Yes. So we did not go back and close that feedback loop because, frankly, the TGA were told: 'ANZTPA is on hold. You should not spend any more time, effort and money doing anything about it.'

The last round was when we put out, on behalf of the NCCTG, the Draft Scheduling Policy Framework and the Draft Standard for the Uniform Scheduling of Medicines and Poisons, in April this year. That consultation period closed at the end of May and any time soon the NCCTG should be authorising us to put a document on the website saying what people said and what our reaction to that was.

CHAIR—Were people advised that the form of feedback would be on a website? Were people advised that that would be how they would get information back?

Mr Maskell-Knight—Did we do that from last time?

Mr O'Connor—I cannot recall.

CHAIR—On notice, can you look to see if that was there, because it seems to me that a number of witnesses today have particularly said, 'We put this up and we have heard nothing back about whether it would work or not.' It was quite a personal thing.

Mr O'Connor—I am not sure whether we put a notice up, but it has been quite obvious through the process that when we put up the initial call for submissions, when we received the submissions and after the closing date for submissions we have published those submissions on the website and when we published the outcome of this we would have advised all of the people who submitted that the outcome was going to be published on the website. So if we have not actually included it on the website at this stage we would have advised them in due course.

Mr Maskell-Knight—The suggestion was made that we should essentially do what the government does in reports of Senate inquiries and other such things and go through it recommendation by recommendation. That sounds fine, if you have one set of recommendations to respond to. In the last round of consultation well over 15 people submitted things. If we were to go through recommendation by recommendation, the cost recovery impacts of that are going to be quite significant. It is a lot of work to go through line by line—'You said this; we do not agree because—'. That is why we want to put up a document shortly that will group like comments. It will provide a brief rationale for why we are not adopting a particular comment. But frankly our resources do not allow us to go into chapter and verse about it.

CHAIR—The Australian self-medication industry have put a number of specific recommendations and they put on record that they had not had any acknowledgement or feedback about it. I take it that that has been over a long period of time. I do not think it would be just as a result of the April-June one. I do not know; we did not ask them those particular questions when they were here. But it seems that they had very specific recommendations. What you are saying, Mr Maskell-Knight, is that it was not process for the department. They have about eight or nine quite specific things in their submission. When questioned they said that all of those things had been raised with the department over a period of time—and they are quite specific. The expectation would be that they would find out what was happening to each of those processes by looking at the website. Is that how it would work?

Mr Maskell-Knight—Our general proposition is that if people have responded to the call for submissions on the consultation documents we will put a document on the website saying ,'This is what we decided in relation to each of those things,' and saying why. If the conversation is about the ASMI attachment 4, which are the proposed amendments, I had not seen those before last Friday or whenever it was that their submission went up. Having said that, I think there are some issues with the drafting of a number of those and I do not think they necessarily require legislation. But there are some issues in there that we will think about.

CHAIR—ACCORD has put 11 specific questions, which we will give to you because I think they are quite detailed and we would like to have some response back on those. When I specifically raised with them the statement from your submission—not to their particular question about the issue of having two lots of schedules and what the response was about the states wanting to have more straightforward processes—their response when I read that, and you were there at the time, was words to the effect that 'it needed more detail' and that, 'yes, they had got that information but the reason you were going down this track was that it was what the states wanted'. The response from the ACCORD people was that it needed more detail to make that clear to them. They saw that that was your answer and that that was what the states wanted. They sought to be more aware of what was going on and to think about what their questions would be to have more detail from that. Is that something that you understand—that response—or not?

Mr Maskell-Knight—Frankly, I think that if the states say 'we want it to be this way' and the states are responsible for implementing it then that is a pretty compelling argument. I do not know how much more refinement you can put into it. You can say 'the states want it this way because changing it will mean more work, and the states are averse to changing their legislation just because we are changing ours' but I am not sure there is a whole lot more detail we can provide.

CHAIR—I am sure that other committee members will want to pick up on some of this stuff, and then we will go to other questions. It seemed to be a threshold issue. We have more specific questions but I thought that was one that came up consistently in the evidence so I wanted to put it on the record.

Senator BOYCE—Yes, I would like to continue on from that point. The ACCORD submission says that they were advised that the legislative approach being adopted in the bill was preferred because it avoids the need for new state and territory legislation. The states and territories advised you that they did not want to develop new legislation.

Mr Maskell-Knight—Indeed. I should perhaps say that scheduling is one of those wonderful things which is a joint Commonwealth-state effort.

Senator BOYCE—And we have had quite a lot of evidence on that topic.

Mr Maskell-Knight—Indeed. I can go back to the memories of one of my colleagues. He used to assist his father, who was a pharmacist, in his shop when he was young. One of his jobs was re-labelling stock that had come from Victoria because in Victoria it was schedule P6 and in New South Wales it was schedule something else. It was a completely different category and everything else.

Senator BOYCE—So it has improved somewhat but is by no means ideal even now, is it?

Mr Maskell-Knight—I would argue that it is considerably improved, certainly in relation to these substances. I happen to have with me a table which sets out the differences, which I am happy to table, where substances are treated differently in particular states. There is a list of perhaps 30 or 40 substances. There are 3,500 substances on the standard. A number of these things are one-off idiosyncrasies to deal with sole traders in Western Australia and Queensland who think they can cure cancer with a particular preparation. No-one else thinks that and no-one else sees the need to schedule those particular things. So there are minimal differences.

Senator BOYCE—Would any of those be much-used products?

Mr Maskell-Knight—No, they are not widely-used products. If you are thinking about the things that are mostly used in over-the-counter substances—paracetamol, ibuprofen and so on—then they are not there. They are almost always treated the same. So I am talking about things like Western Australia scheduling *Scaevola spinescens*, which has been used for the treatment of cancer by a sole trader. Queensland has felt the need to schedule alkaloids and alkaloidal glycosides of plants of the genus *Solanum* for human therapeutic use because, again, some sole trader there has had a bright idea what they can use those for.

Senator BOYCE—Which schedule is this?

Mr Maskell-Knight—This year they put them into schedule 4 by the looks of things.

Senator BOYCE—But storage and use of chemicals was also an issue that was raised as not being uniform.

Mr Maskell-Knight—That is true, and it is not. But again if you are running a company trading across state lines then the simplest solution is to adopt the most restrictive requirements of any jurisdiction in relation to storage of schedule 5 and schedule 6.

Senator BOYCE—That is great if you do not have conflicting requirements, which often happens in numerous areas which affect manufacturers—not just in this particular field but across industries.

Mr Maskell-Knight—The schedule 5 and schedule 6 requirements go to whether you store things 1½ metres above the ground or 1.2 metres above the ground or whether you do not care. So it is not conflicting; you just put them up off the ground as high as you can and then you will be right.

Senator BOYCE—I must admit that I do not have a lot of retail experience, but I would have thought that anyone who runs a shop would tell you that every 0.1 of a metre you want to put that higher is going to cost them money in terms of use of space.

Mr Maskell-Knight—I reckon that if you have them low down then people will not see them.

Senator BOYCE—What you is your background in retail, Mr Maskell-Knight?

Mr Maskell-Knight—I have sold alcohol.

Senator BOYCE—And?

Mr Maskell-Knight—And it was at every level from the ground up. I do not recall any children taking something off the shelf and drinking it.

Senator BOYCE—So you owned a hotel, did you, Mr Maskell-Knight?

CHAIR—Senator, the terms of the bill, please.

Senator BOYCE—Yes. I think an understanding of practical industry requirements at each level is quite critical to the bill. Getting back to that general view about consultation, I think we have had 'summarily disregarded', 'completely ignored' and 'take it or leave it' as descriptions of how industry players felt the consultations were conducted. What is your response to that?

Mr Maskell-Knight—As I said when you are absent from the room before, unfortunately, there have been essentially three phases of consultation.

Senator BOYCE—I heard some of that.

Mr Maskell-Knight—In the first phase there was feedback provided. The second phase fell in a heap when ANZFA fell in a heap. In the third phase there will be feedback provided shortly.

Senator BOYCE—When would you anticipate that feedback would be provided?

Mr Maskell-Knight—I am optimistic—he said, looking at his colleague—that it will be later this month.

Senator BOYCE—What has to happen for that feedback to be ready to be provided?

Mr Maskell-Knight—The National Coordinating Committee on Therapeutic Goods has to agree to the document being put up on the website.

Senator BOYCE—Was there any consideration given to how that consultation dovetailed with the bill itself?

Mr Maskell-Knight—There was, and we took the view that the bill basically sets out a very high-level framework. There would have been no surprises, I do not think. The model that it sets out was basically recommended in the Galbally review. It was adopted by AHMC in 2005. The Productivity Commission report outlined it in some detail in 2008. It should not have been of any surprise to anyone that we were going to have a common decision maker, two committees, a common standard and charge, and a cost recovery regime. That is essentially the level of detail the bill goes into.

Senator BOYCE—I guess you would not have observed from the submissions that, firstly, there was a level of dissatisfaction with the very high level of the bill. There are a number of submitters who feel that there should be more detail in the bill itself, not kept on the side for legislative instruments and regulations. Also, some of the submissions would suggest that in fact people were quite surprised. We had one witness earlier—I am forgetting which one now—who made the point that suddenly there had been a change from the use of the term 'poisons' to the term 'chemicals'.

CHAIR—The Pharmaceutical Society.

Senator BOYCE—Sorry, that was the Pharmaceutical Society. They said that this had never been flagged before.

Mr Maskell-Knight—The term 'chemicals' is used in relation to the title of the advisory committee, and that title was chosen because our colleagues from ACCORD and others expressed concern that we were referring to their products as being poisons rather than chemicals. In terms of the poisons standard, it is still the poisons standard, as it always has been.

Senator BOYCE—And the explanatory memorandum used the terms 'chemicals' and 'poisons' interchangeably, they said.

Mr Maskell-Knight—That is quite incorrect. It uses the term 'chemicals' when it is referring to the chemicals committee and it uses the word 'poisons' when it is referring to the poisons standard or, indeed, the generic group of things that are medicines and chemicals. I was alarmed when I saw that comment, I must say, because I thought I had read the explanatory memorandum fairly carefully. I went back, and it does not use the terms interchangeably. It uses both terms, but it uses them appropriately.

Senator BOYCE—At least you were not surprised. You were alarmed. I want to try to get a little bit more understanding of what legislation it is that the states would be required to change.

Mr Maskell-Knight—If you look at attachment 2 of our submission, you see that essentially the states have a piece of legislation that basically is for 'drugs and controlled substances' or some gloss on that.

Senator BOYCE—So are we talking about roughly one piece of legislation per state or just one piece of legislation?

Mr Maskell-Knight—I think it is one act in every case—although, having said that, I notice New South Wales has a 1966 act. Sorry, I think it is one act.

Senator BOYCE—Did you ever look at what would be involved in those changes being undertaken?

Mr Maskell-Knight—I cannot answer for what happened before the middle of last year. I can certainly recall the fact that it took something like 20 years to get a common corporations act. It took about 10 years to get a common human tissues act—and they are still not common. So I cannot speak for whether anybody in the past has looked at trying to get the states to change that. Since I have been involved in this process, it has been very clear from AHMC downwards that the states will only countenance this if they do not have to change their legislation to refer to chemicals and medicines standards.

Senator BOYCE—One other issue that was raised was the move to put over-the-counter medicines and the like into a very risk-averse assessment process through TGA. This was not warranted with regard to a lot of the products that would be assed.

Mr Maskell-Knight—I think risk averseness is one of those characteristics which medicines regulators—and probably all sorts of other substance regulators as well—have. For schedule 4 prescription medicines I think the regulator has regard to the fact that there are often considerable benefits from the use of those medicines in addressing quite serious illnesses.

Senator BOYCE—But we are not talking schedule 4, are we?

Mr Maskell-Knight—I am working my away inexorably toward your answer. For schedule 4 you accept a degree of risk because there is a very substantial degree of benefit that cannot be achieved elsewhere. Once you get down to schedule 3 the benefit-risk trade-off changes, I think. Once you get down to schedule 2 you are essentially talking about things that alleviate symptoms; they do not cure illness. In the context of symptomatic relief I think the public would expect a fairly risk-averse view of the world. They would not want to think that something they are taking for symptomatic relief is going to have serious side effects, even if those side effects are very rare. I suppose that once you get to the stage of having vitamin and mineral supplements and herbal things that promote good health, as a member of the public I would want to be very sure that they were not going to do me any harm. Even if it were a very remote chance, I still would not want to take black cohosh, for example, unaware of the potential hepatotoxic impacts that can have.

Senator BOYCE—I missed part of your answer to the earlier question about the chemicals and medicines committees. You suggested that the chemicals committee would be working with the Office of Chemical Safety. Is that correct?

Mr Maskell-Knight—I expect the delegate of the secretary in relation to chemicals scheduling will be in the office of chemical safety, yes. So the advice from the chemical scheduling committee will go to the delegate in the office of chemical safety.

Senator BOYCE—Sorry, I do not understand public service processes enough to know what that is going to mean in practice.

Mr Maskell-Knight—The TGA is a division of the Department of Health and Ageing. The Office of Chemical Safety and Environmental Health lives within the Office of Health Protection, which is another division. So the proposal at the moment is that the secretariat will be a common secretariat for the medicines committee and the chemicals committee. It will reside within the TGA. The delegate for medicines decisions will reside within the TGA, the delegate for chemicals decisions will reside within the office of chemical safety, and the chemical scheduling committee will provide advice to the delegate there.

Senator BOYCE—Where is this going to be spelt out?

Mr Maskell-Knight—It will be spelt out in the administrative arrangements. I am not sure whether the scheduling policy framework spells a fair amount of that out.

Mr O'Connor—It certainly does.

CHAIR—Is that public, Mr Maskell-Knight?

Mr Maskell-Knight—That was the document that was released for consultation in April, Senator.

Senator BOYCE—Would you anticipate that that would satisfy the concerns raised by the witnesses today?

Mr Maskell-Knight—I do not think so, no. I think we have given them a set of free steak knives and they want a Crown Derby dinner set. So I do not think it will. We are splitting the committees, which is what Galbally said, but we are still having a common secretariat. There was a view around that we should have different secretariats. My view is that it will not make any substantive difference to the outcome; all that having different secretariats does is that it will make it harder to coordinate common activities across the two committees, and there are quite a few substances that are both chemicals and medicines and there would be significant benefits in having a common secretariat to join those things up, and it would also—

Senator BOYCE—One of the witnesses earlier today described that view as a furphy.

Mr Maskell-Knight—Well, that is their view. They are not a public servant with experience in committee secretariats, I guess. The other point about it is that two committee secretariats will inevitably cost more than one.

Senator BOYCE—Sorry, my comment was not related to committee secretariats; the view that was described as a furphy was that there were so many substances that were both a medicine and a chemical that to say this was warranted was described as a furphy.

Mr Maskell-Knight—There are a substantial number. We have not gone through the schedules to count them but there are a not inconsequential number of things that are both human medicines and veterinary medicines. Essential oils can be both chemicals and have a medicinal use.

Mr O'Connor—It was certainly an issue that was raised in the Galbally report. The states and territories, in agreeing to separate the National Drugs and Poisons Schedule Committee, set out three criteria or provisos for agreement for the separation. The common secretariat was one, for the need for coordination and cohesiveness between the two committees; the second one was a single schedule policy framework; and the third one was a single poisons standard, which we are trying to deliver through this bill.

CHAIR—That goes back to 2001.

Mr O'Connor—It goes back to 2001. In 2008 it was reiterated by the Productivity Commission, and my understanding is that COAG has accepted the interim response to the PC report.

CHAIR—How many people are normally in a secretariat, Mr Maskell-Knight? I know it varies according to resources, but in your experience, when you are talking about a secretariat for bodies like this, what number would it normally be?

Mr Maskell-Knight—I think there are about five in the current National Drugs and Poisons Schedule Committee secretariat.

CHAIR—So that would be the idea of having a resource of about five people who would act as a joint secretariat to the two bodies?

Mr Maskell-Knight—Yes.

CHAIR—Which would seem to be not uncommon in the public sector to have those types of numbers. Senator Siewert?

Senator SIEWERT—I am still on consultation, and then I think we probably need to move on to a few other things. The CHC raised the issue of consultation over advisory statements before they become legislative instruments. I need to clarify whether they are disallowable or whether they are the ones that are not disallowable.

Mr Maskell-Knight—They will be disallowable. And the Legislative Instruments Act mandates you must consult on legislative instruments, and we do consult on RASML at the moment. We will continue to consult in exactly the same way.

Senator SIEWERT—I suppose it is a definition of consultation—a point which we have been discussing at length, I appreciate—but what they were saying is early on in the process rather than at the last minute. With all due respects, all along this table we have all had experience with good consultation and bad consultation over legislative instruments. I will get on to some of the other issues in a minute, but they were being, I thought, very reasonable around saying, 'On this one we are not saying we disagree; we are just saying we want an acknowledgment or a commitment that there will be appropriate and timely consultation rather than at the last minute.'

Mr Maskell-Knight—I think RASML has been around for about 20 years and I think we have always consulted appropriately. I must say I am unaware of anyone suggesting that we have not.

Senator SIEWERT—There have been people here today saying you have not.

Mr Maskell-Knight—Not on RASML. They have suggested all sorts of other sins we may have committed, but I think we are free on that one.

Senator SIEWERT—I am talking specifically about that bit of consultation. Where do you usually start when you are consulting on that particular issue?

Mr Maskell-Knight—I do not know. I would have to take that on notice.

Senator SIEWERT—It would be appreciated if you could. Thank you. I would like to move on to advertising. The changes to advertising seem to be a concern to a number of organisations. You will be aware of comments that were made in terms of the review that is currently being undertaken by the sector itself and

the desire to see the learnings from that process incorporated into the bill or into the processes that are used. I also understand you are undertaking your own review.

Mr Maskell-Knight—We are working towards producing a consultation document about how we think the advertising regime can be simplified and improved, yes. I am interested to hear that CHC have been doing a lot of work on that and I look forward to hearing what they have to say. I should say they have not consulted me yet, but I am sure that is an omission they will quickly rectify. In terms of whether we should fix up this offence provision pending the bigger thing, I think that this is a discrete problem that we have at the moment and that we should not wait 12 months to fix it up. If you go online, Senator, you will be able to find lots of online pharmacies bruting products completely outside the indications that are on the register for them. At the moment there is no provision—there is nothing we can point to—that says, 'Thou shalt not do this because it is a criminal offence.'

I should also add, in terms of, 'What if someone gets an advertisement approved and the indications then shift? Will they not then be liable for prosecution?' the Director of Public Prosecutions, before prosecuting anyone, has to form the view that it is in the public interest. I do not think he is ever going to form the view that it is in the public interest to prosecute someone for publishing an advertisement that the secretary of the department had given delegated approval to. Even if by some strange quirk of circumstance that were to happen, the prosecuted person could rely on section 9.1 of the Criminal Code Act, which says if you act in a mistaken belief about or are ignorant of particular facts then you are off the hook. So I think that is a very far-fetched possibility that CHC outlined.

Senator SIEWERT—I was quite surprised that there do not seem to be stats kept on the number of reviews of ads and the number of appeals et cetera.

Mr Maskell-Knight—That is not entirely correct. Every complaint considered by the Complaints Resolution Panel is put up on the Complaints Resolution Panel website, including what the product was, who complained about it, what the complaint was, what was upheld and which sections of the code were breached. I would be surprised if it were not in an annual report of some sort somewhere, but it is a reasonably trivial matter to go to the website and sort them all out however you wish to.

Senator SIEWERT—It was not just the complaints but that the complaints that go, as I understand it, to the CHC process are being treated differently.

Mr Maskell-Knight—We do not know about the CHC process.

Senator SIEWERT—In terms of the preapprovals process, as I understand it from the question I asked earlier, there are no stats kept on the numbers approved, the numbers not approved et cetera. Is that something that you—

Mr Maskell-Knight—My understanding is that both CHC and ASMI write a report to the TGA every 12 months saying how many they have approved and how many they have not.

Senator SIEWERT—I will make sure we ask some questions on notice about that, because it was my clear understanding that in fact they could not tell us those stats. Maybe it was the way I asked the question or interpreted the answer, so I will chase that.

Mr Maskell-Knight—I did not understand that that was the question you were asking, so they may not have understood it that way.

Senator SIEWERT—Okay. I will chase that. Thanks.

Senator FURNER—I think you have answered, in your view, the confusion of poisons with chemicals in the submissions of the Pharmaceutical Society of Australia, but they made some specific comments on concerns about proposed section 52E(1) and they listed them as: the safety of a substance, the patterns of use of a substance and the need for access to a substance. I would be happy to hear your comment on whether they have been addressed in the proposed bill.

Mr Maskell-Knight—When we drafted these amendments we redrafted section 52E(1). The reason we did that was that, while it might have looked all right on paper, when people tried to address those criteria they found themselves saying the same thing twice, if not three times, under different lines of those categories. What we are now saying is that we must have regard to the risks and benefits of use; the purposes and extent of use; toxicity, dosage formulation, labelling, packaging and presentation; the abuse potential; and anything else. The PSA are saying that we should have regard to: safety—our view is that 'the risks and benefits' covers that; the patterns of use—our view is that 'the purposes for which a substance is to be used and the extent of

use' effectively covers that; and the need for access to a substance—again, that comes under 'the purposes for which a substance is to be used'. So we think those criteria are actually covered.

Senator FURNER—What part of the bill is that?

Mr Maskell-Knight—Clause 52E(1).

CHAIR—I have one question on the same area. You were in the room when the self-medication group—

Mr Maskell-Knight—Australian Self-Medication Industry.

CHAIR—Australian Self Medication Industry. I am not going to go into all those initials; I am just not doing it. They raised concerns about clause 52E(2). Their perception is that the subcommittee, the new National Coordinating Committee on Therapeutic Goods, will be a faceless group of non-accountable people and that the only 'must comply' in all of clause 52E is subclause (2). The other clauses are 'the Secretary must take the following matters on advice', 'must have regard to', 'may' and 'may consider'. But clause (2) says the secretary 'must comply with'. Their concerns were that that is clearly a definition, so it must happen, and that that is not really an effective, open and transparent way of having the issues considered. Can you give me some information that would allay that fear?

Mr Maskell-Knight—Firstly, it is no different to what happens now.

CHAIR—I am not sure whether that makes me feel any better. Nonetheless, it is not making a change.

Mr Maskell-Knight—It is not making a change. Secondly, the secret guidelines are the ones we have just been consulting on. If they were really going to be secret we would not have. Thirdly, for the most of the last three months I have, for my sins, been the acting chair of the committee of faceless, secretive ones.

CHAIR—So you have been the acting chair of the national coordination committee?

Mr Maskell-Knight—Yes. In that capacity I have received two requests for the committee to give guidance to the National Drugs and Poisons Scheduling Committee, and they have both been from industry saying, 'Why won't you tell the National Drugs and Poisons Scheduling Committee to do what industry wants?' So there is a capacity for it to be a double-edged sword, I would argue. The scheduling policy framework has been consulted on. We will continue to consult on any future iterations to it. The National Coordinating Committee on Therapeutic Goods is responsible to AHMAC, which is responsible to AHMC. It is made up of the states and territories that are responsible for implementing this framework at the end of the day.

CHAIR—And the Australian Health Ministers Advisory Council is there as well.

Mr Maskell-Knight—Yes.

CHAIR—I just thought, from my perspective in the public service, that was a particularly important element to be addressed.

Senator BOYCE—We have had a few views on what was going to happen with fees regarding listing of products under both the medicines and the chemicals schedules. What is the current intention?

Mr Maskell-Knight—The current intention is to release a draft cost recovery impact statement later in the year that will spell out all that.

Senator BOYCE—Later in the year being?

Mr Maskell-Knight—Later in the year. Once we can clone Mr O'Connor and he can do three things simultaneously then we might be able to do it sooner, but at some stage before the end of the year.

Senator BOYCE—So you will be developing a schedule of fees based on cost recovery—is that the current situation?

Mr Maskell-Knight—Yes. The Therapeutic Goods Administration works on cost recovery at the moment. There were suggestions that we do not want to be cross-subsidising chemicals and so on. We do our very best to make sure that each activity we undertake is covered by the fees we charge for that particular activity. We have greater or lesser success with that, but those greater or lesser successes are at the margin. We certainly do not intend that the chemical industry will be getting a free ride from the therapeutic goods industry, nor do we want the chemical industry to be paying more than its fair share.

Senator BOYCE—I suppose, given that a number of people are concerned about the level of fees likely, there is very little comfort for them in the comment that you have just made.

Mr Maskell-Knight—I think there is a level of concern and there is a level concern. We are talking about the cost of five staff and a number of committee meetings. I do not think it is going to be a huge amount of money.

Senator BOYCE—I think the figure of $560 was mentioned earlier today. Do you know where that came from?

Mr Maskell-Knight—That is the annual fee to maintain a listing of a complementary medicine on the register.

Senator BOYCE—To maintain it, but not to have it listed.

Mr Maskell-Knight—No, I do not know what the initial listing fee is. I think it is $5,000 or $10,000—of that order.

Senator BOYCE—You might be able to give us that schedule. That might be helpful.

CHAIR—Do you know where the figure of an increase of 14 per cent came from?

Mr Maskell-Knight—That is what we are going to put the charges are up by.

CHAIR—So that is a given—14 per cent. They know that.

Mr Maskell-Knight—Yes, 14.3 per cent.

Senator BOYCE—That is for existing complementary medicines.

Mr Maskell-Knight—Yes. It is for all of the charges we currently levy on complementary medicines.

CHAIR—And is there a known percentage increase for the chemicals as well?

Mr Maskell-Knight—We do not do anything with chemicals at the moment.

Senator BOYCE—Yet.

Mr Maskell-Knight—Yet.

CHAIR—So there is no awareness yet of what those fees will be?

Mr Maskell-Knight—No.

Senator FURNER—While you were responding to Senator Boyce on these, I was writing some notes down from previous matters raised. Is there any possibility of cross-subsidy from the therapeutics industry to the chemical industry as a result of the changes?

Mr Maskell-Knight—No. As I said, at the moment we regulate six or seven different industry sectors and we do our best to make sure they each pay their own way. We will continue to do that under the new arrangements.

Senator FURNER—Earlier today CHC suggested that there should be complementary medicines expertise on the new medicines scheduling committee. What is your position on that?

Mr Maskell-Knight—We want to have an expert committee. The sorts of things we want the secretary to be advised about are things like toxicology and pharmakinetics. The toxicology of complementary medicines is the same as the toxicology of anything else, and so is the pharmakinetics, so we do not see this committee as one to have complementary medicine expertise, over-the-counter expertise, prescription medicine expertise and so on; otherwise, you will need to hire Albert Hall to have committee meetings. So it is more about scientific expertise that would cover a whole range of medicines. That is what we see the committee membership being.

CHAIR—Mr Maskell-Knight, there will be some questions on notice but we have to work out what those questions will be before we give them to you. I will certainly be providing the 11 points that were given to us by ACCORD. Some of those may not be able to be answered immediately, but as they were raised specifically in this hearing we would not be doing our job—

Mr Maskell-Knight—I am happy to give you some answers to some of them now if you wish.

CHAIR—We have to catch a plane to Melbourne—you are protected by that!

Mr Maskell-Knight—I am very happy to help you. Can I say though that with question B, in particular, I do not understand what it means, so I would have great difficulty answering it.

CHAIR—If you could answer those 11 questions as best you can—

Mr Maskell-Knight—Certainly.

CHAIR—and then we will get back in contact with the ACCORD people. At least we will have completed the process of getting some of those specific answers. We will get back to you as quickly as we can regarding other questions we want to follow up on. This is a bill that we have been waiting for in regard to the Galbally stuff. It has been on the record for a long time and we would like to make sure that people are moving forward. One thing that can be said is that all the witnesses who came forward made clear statements that they wanted to move forward as well—every single person who came and gave evidence and submissions said that they wanted to move forward and they just had issues that were concerning them. I think that is positive in itself. Thank you for your evidence.

Committee adjourned at 4.52 pm