***The Pan recall** of complementary products covered over 1 billion doses and yet only 62 adverse reactions were noted. Of those only 2 could be shown to have been actually manufactured by Pan and those 2 reactions involved hypertension and an allergic reaction. Amazingly though the Pan recall was carried out as a Class 1 recall - the most serious possible, supposed to be used for potentially life threatening situations. Compare this to the recall of Vioxx, a prescription medicine linked to significant numbers of heart attacks, which was recalled only as a class 2 recall - the recall for defects that could cause illness or mistreatment. It's hard to see what else you need to see the inherent pro pharmaceutical bias of the TGA. Below, read the reports of the debate in the Australian senate where TGA officials are taken to task over this very point.*

Pan = Class 1 (Class I defects are potentially life-threatening or could cause a serious risk to health

Vioxx =class 2 (Class II defects could cause illness or mistreatment, but are not Class I.)

Class III defects May not pose a significant hazard to health, but withdrawal may be initiated for other reasons.]

Subject: Proof Committee Hansard SENATE COMMUNITY AFFAIRS LEGISLATION COMMITTEE THURSDAY, 2 JUNE 2005

COMMONWEALTH OF AUSTRALIA

Proof Committee Hansard

SENATE

COMMUNITY AFFAIRS LEGISLATION COMMITTEE

ESTIMATES

(Budget Estimates)

THURSDAY, 2 JUNE 2005

CANBERRA

CORRECTIONS TO PROOF ISSUE

This is a **PROOF ISSUE**. Suggested corrections for the Bound Volumes should be lodged **in writing** with the Committee Secretary (Facsimile (02) 6277 5829), **as soon as possible but no later than:**

Thursday, 4 August 2005

BY AUTHORITY OF THE SENATE

[PROOF COPY]

CHAIR—I thank the witnesses for appearing. I call witnesses from the Therapeutic Goods Administration.

[11.41 am]

Therapeutic Goods Administration

Senator ALLISON—I refer to the Pan Pharmaceuticals recall and follow up on answers provided to questions I raised not long ago. With regard to the 62 reports of adverse events or reactions attributed to Pan Pharmaceuticals—and I thank the TGA for that advice—can I confirm how many of those 62 adverse reactions reported can with certainty be attributed to Pan? In other words, how many were definitely manufactured by Pan?

Mr Slater—Of the reports received from the Pan recall, there were eight with batch numbers confirming that the product indicated had been manufactured by Pan. That was for products that were received after 28 April 2003. For those adverse reactions received prior to the recall, there were 20.
Dr McEwen—There were 20 reports received before the recall but it is my understanding we could not tie Pan to any one of those because Pan was one of a number of nominated manufacturers, and we did not have the batch numbers provided for those.
Senator ALLISON—So eight is the total out of 62. We can only be certain that Pan manufactured eight; is that correct?
Dr McEwen—I believe so—I think because of the way the work was done. I will need to take the responsibility to double-check that with respect to the 20, but that is my belief, yes. If it is incorrect, we will have that advice to you.
Senator ALLISON—In fact, there is one on the list which refers to Rocaltrol. Is it not the case that that is definitely not a product manufactured by Pan?
Dr McEwen—Again, I am sorry—I do not have that list. Mr Slater may have those. Certainly my belief is that Rocaltrol was not manufactured by Pan, but the possibility—and I would want to check this and advise you—is that, as well as a Pan product, this was another medicine also taken, and they were both regarded as possible causes of the reaction.
Senator ALLISON—I do not think that is what the report says, but you might check that. It would be useful to have an explanation as to why it is on that list and included in the 62 if that was not the case.
Dr McEwen—We will do that for you.
Senator ALLISON—Can TGA confirm that all of those products referred to were in fact manufactured by Pan within the time frame under consideration? In other words, are you certain that the time frame that is referred to, both before and after, includes all those listed events?
Mr Slater—As a result of your question, we have gone back and totally reviewed the data. We have moved from 62 to 66 particular instances as a result of that review.
Senator ALLISON—So you have increased it?
Mr Slater—Yes. And we can confirm that they are relevant to the period that you are seeking.
Senator ALLISON—So is there a new list that you can provide the committee with?
Mr Slater—We are happy to provide you with a new list, yes.
Senator ALLISON—Now?
Mr Slater—No, we will take that on notice and give that to you.
Senator ALLISON—Is it not the case that none of the 24 reports relating to organ damage were found to have been certain or even probable by the Adverse Drug Reactions Advisory Committee? Is that a fair reading of the report?
Dr McEwen—Yes.
Senator ALLISON—In fact, isn't it the case that only two of those reports have batch numbers that confirm with any certainty that the product manufactured by Pan was involved?
Dr McEwen—I believe that is correct.
Senator ALLISON—And can you confirm that those two reactions were an allergic reaction and one for hypertension?
Mr Slater—I think the issue here that we need to give some clarity about is that, while you are saying that we can only say with certainty that there are eight products that were definitely—CA 38 Senate—*Legislation* Thursday, 2 June 2005 COMMUNITY AFFAIRS
Senator ALLISON—No, two.
Mr Slater—No, I am going back to the original, where we started. There were eight products where we can be absolutely certain that Pan was the manufacturer. In the 66 cases that we are referring to, Pan may well have been the manufacturer—
Senator ALLISON—Indeed.
Mr Slater—and hence the data that we have given you shows some very serious adverse reactions that relate to those products. We cannot with certainty say to you that they were manufactured by Pan, but there is a probability that they were.
Senator ALLISON—Indeed. I did use the word 'certainty'. So did we establish that the other was for hypertension?
Dr McEwen—I believe that is correct.
Senator ALLISON—Is it also the case that only three of the 62 reports did not involve any complementary medicine products at all but only pharmaceutical drugs?

Dr McEwen—I think that is correct as well.
Senator ALLISON—And is it not the case that, in more than 50 per cent of the cases cited, people were also taking pharmaceutical drugs, not just complementary medicines—in other words, antidepressants, COX-2 inhibitors, blood pressure medications and anti-inflammatories? Can you confirm that?
Dr McEwen—I do not have that split, but it may well be correct. I am happy to confirm it or, if it is not correct, to advise you of that.
Senator ALLISON—Can you also confirm that the adverse reactions that were listed are all known to be the results of those pharmaceuticals, regardless of where they are manufactured—that these are not uncommon adverse reactions to the pharmaceutical drugs I have just listed?
Dr McEwen—I do not have that split with me, so I am reluctant to say yes. I would be prepared to say that, where there are other pharmaceuticals being taken, it might commonly be that that could be attributed to that drug, as distinct from—
Senator ALLISON—So why were they included in the list?
Mr Slater—There were 40 of the 56 reports where at least one other medicine was being taken. But the Adverse Drugs Reaction Advisory Committee, which is a committee of experts in the field, often at professorial levels—certainly, of eminent clinicians in Australia—as we have provided to you in answers, went through each report and coded a view as to whether the medicine that was involved, manufactured potentially by Pan, was in fact a potential or a suspect in the adverse reaction. That data has been given to analysis, from where it may well have been considered as a certainty down to where it was considered to be a possibility.
Dr McEwen—Could I extend that further. The committee has had a standard way of looking at incoming reports for more than 20 years. It has applied that throughout the period and it was applied to the Pan reports as well. One of the circumstances is that if a report describes two medicines being taken, particularly if two medicines have been started relatively close together, and either of those two medicines are continued after the adverse event or those two medicines are both ceased and there is recovery after the adverse event, both of those medicines would be regarded as possible causes of the action unless there was some other evidence relating to that case, not to the literature in general, that said, 'We can distinguish between the two.' That is the explanation in this instance, I believe—that it is the application of a coding method that has been used by the committee for 20 years or more.
Senator ALLISON—So where people—and there were 50 per cent in this category—were taking multiple medicines, is it the view of the TGA and your experts who assisted you with this list that those people are at greater risk of adverse drug reactions by virtue of the multiple medicines that they are consuming? In other words, is the issue when you are using two kinds of drugs about choosing which one caused the reaction or is it more that you are more likely to get a reaction if you mix up a range of drugs?
Dr McEwen—As they are assessed and as they are recorded, it is the first: either medicine might be the cause of the reaction—unless there is other evidence to point to one or the other—rather than, as I think you are suggesting, an interaction between the two medicines. Now, there are some instances where the committee adopts a different coding system—they are relatively few—and that is where there is a well-known attributable interaction. One can think of examples where one substance is clearly known to interact with another; it would Thursday, 2 June 2005 Senate—*Legislation* CA 39 COMMUNITY AFFAIRS then be coded in a separate way which says, 'This is a suspected interaction between the two.' That is very uncommon, though. The great majority would be recorded with both of them as possible causes, each being considered in its own right and not as an interacting medicine.
Senator ALLISON—Is there a document that would be useful to the committee in understanding which of these are likely to cause adverse reactions in combination with others?
Dr McEwen—The overall causality assessment was provided as an attachment. It does not go to the matter of interactions. We can get you some information. The other thing we can do is go through all of those reports and say, 'Of those, have we not identified one where the literature would suggest there is an interaction?' I suspect there weren't, though.
Mr Slater—In answer to your question in January this year, we provided you with 62 reports, which there were at that stage, with a detailed report on each one of those.
Senator ALLISON—Correct. That leaves us with only two instances, unless the increase—what is it, an extra six cases since you produced that list?
Mr Slater—Yes.
Senator ALLISON—Would that have changed the fact that there were only two instances with any certainty that the product manufactured by Pan was responsible?

Dr McEwen—It was the sole suspected drug, I believe.
Mr Slater—Yes, which was the sole suspected drug.
Senator ALLISON—So that has not altered? The ones you have added, which we do not have the benefit of being able to see—
Mr Slater—Altogether there were 66 reports of adverse reactions where Pan may well have been the manufacturer.
Senator ALLISON—Can you explain how allergic reaction and hypertension—the two reactions that we referred to—fit within a class I recall level?
Mr Slater—If you are asking why we did a class I recall, it was not on the basis of adverse reactions; the majority of these adverse reactions have come to light subsequent to the Pan recall. As I have explained to the committee in the past, the class I recall was based on the fact that there were such manufacturing deficiencies in the quality of the products that, in the opinion of an expert committee of eminent professors and clinicians, in aggregate there could be no confidence in the safety of these products. In their recommendation, those products represented the possibility of imminent, serious illness which could result in death or serious injury. Their recommendation was to do an immediate recall and to suspend the licence.
Senator ALLISON—So, at the end of the day, were you surprised that there were so few? Sixty-two reports of adverse reaction, when the manufacturing process was so unsatisfactory, are not a lot. For 1,600 products, I think there were about 11 billion doses over a 12-month period. Is that what the TGA would regard as significant, even if the 62 reports were attributable with certainty to those adverse reactions? Is that less than you would expect?
Mr Slater—I think the context of this is that these were largely manufactured as low-risk medicines. Therefore you would have expected not to have a situation where there were adverse reactions or safety concerns. We did not go out and ask whether people felt unwell as a result of taking a particular product. These are products that have come to the TGA as formal reports—
Senator ALLISON—There was a fair bit of publicity at the time, Mr Slater, and you took adverse reactions following that. I do not know that you can say—
Mr Slater—What I am saying here is that these reports are formally presented to the TGA, generally by professionals, by medical practitioners. In these events, the most likely source of the report to the TGA was someone presenting to their practitioner with a particular illness or reaction which, in the practitioner's opinion, necessitated a report to the TGA. Practitioners only generate these reports where they feel the regulator should be aware of information that should be taken into account in how a medicine is regulated.
Senator ALLISON—Of course. Can we just draw some comparisons between this recall and that of Vioxx? As I understand it, the class I recall has to be about life-threatening products or products that could cause a serious risk to health. Why was it then that Vioxx was given a class II recall?

Mr Slater—The recall for Vioxx was at the initiation of the sponsor. It arose as a result of clinical concerns, not as a result of manufacturing quality concerns. The manufacturer—
Senator ALLISON—But there is nothing in the definition of class I or class II that talks about manufacturing problems.
Mr Slater—I am sorry; I did not get a chance to finish my answer.
Senator ALLISON—Sorry, Mr Slater.
Mr Slater—In this case, as new data came to hand as a result of their clinical studies, the manufacturer sponsor felt that the risk presented through cardiovascular events was such that they made a decision as a responsible company to immediately do a worldwide withdrawal of this product.
Senator ALLISON—What is the difference between a class I and a class II recall, other than the reason for doing it? What are the implications of that being class II as opposed to class I for Vioxx?
Dr McEwen—The definitions provided are a class I recall occurs when products are potentially life threatening or could cause a serious risk to health. Class II recalls occur when product defects could cause illness or mistreatment that is not class I. We are just checking this. I am uneasy about this as I thought it was not a class II recall, although I may be wrong. But certainly the recall actions taken by the TGA were essentially to relay the fact that the company had withdrawn the product worldwide because of the detected increase in non-fatal heart attacks.
Senator ALLISON—It does not get to be classed as any kind of recall if the manufacturer takes that action themselves. Is that what you are saying?
Mr Slater—No, that is not what Dr McEwen is saying. What Dr McEwen is saying is that Vioxx was a product that was marketed around the world by the sponsor, the manufacturer. In part of the data that was submitted to the TGA

for evaluation, it drew heavily on substantial clinical trials. Those clinical trials—and Dr McEwen can go into this in much greater detail—showed that there was a level of increased cardiovascular events. The view of experts at the time was that those cardiovascular events did not represent an increase as a result of the product itself, but really the products that Vioxx was replacing, the existing anti-inflammatories, had a cardiovascular protecting effect. Hence, the detected incidents in clinic trials were not as a result of the medication itself. In subsequent clinical trials that the company carried out post marketing approval decisions, that information came up for questioning. As a result of the clinical trial that the company concluded, it immediately decided to withdraw that product worldwide due to increased incidence of cardiovascular events.

Senator ALLISON—Did Australia issue some sort of notification? I am not sure what you do when you have a recall, but that was my question. If the manufacturer themselves indicate they are going to recall their product, does it get a classification? Do we say it is class I or class II or class III and, if so, what are the implications? What is the difference between being a class II and being a manufacturer recall?

CHAIR—The question about the Vioxx recall has been canvassed in this committee extensively. It is for the reasons that Mr Slater and Dr McEwen have been talking about. I am wondering, in an effort to save time, whether it would be appropriate to either arrange a briefing about this whole recall or to refer you to past *Hansards* where this issue has been covered extensively. We are really going back over ground about Vioxx that has been gone over and over and over before.

Senator ALLISON—Perhaps it is because it is such a grey area and it is not clear what the various recalls—

CHAIR—No, it is absolutely crystal clear. The information that the officers have given to this committee previously is crystal clear, and there is so much information out there in the public arena about Vioxx as well.

Senator ALLISON—I do not really want to pursue the Vioxx much, but I am interested in the difference between class I and class II in this instance—that is all.

Dr McEwen—The document here clearly reflects that it was a consumer level recall, but it does not reflect whether it was class I or class II. I would like the opportunity to check that. The impact of that, although it was initiated by the sponsor and indeed many recalls are initiated by the sponsor, was that it then followed through on the uniform procedure, which meant that the Commonwealth officers—whom my colleagues met—distributed the information to state and territory health authorities and that flows on through the hospital system. They also followed the advertising requirements. As I recall, they put advertisements in the major metropolitan newspapers saying that our product has been withdrawn—if it was called class II, that class I and Thursday, 2 June 2005 Senate—*Legislation* CA 41COMMUNITY AFFAIRS class II does not get into the public domain—but in my view it was certainly clear to the public that this was because of serious adverse events and that is why people were being asked to stop it and see their doctors.

Senator ALLISON—I recall it now, but is there not a difference in the kind of advertising that is required between a class I and a class II?

Mr Slater—There is also a more significant difference here. This product Vioxx is a prescription-only medicine. You can only get it by attending a medical professional who is registered to provide a prescription. The product is prescribed on that medical expert's clinical judgment as to what your particular patient needs are, the range of optional treatments that are available and which is the best one for you. Hence, when you are looking at a recall here, we know exactly who has been provided with that product. The difference between that and Pan is that any person could walk in off the street and buy a low-risk product from a health specialist or a supermarket and take it on their own self-medication choice. As we discussed earlier, the issue around interactions and so forth is not something that is being monitored by a professional. We have a totally different environment that is operational here.

Senator ALLISON—Does that mean that whether a complementary medicine, which is not a prescription medicine, is classified class I or class II, there is a different advertising requirement because it is not prescription? Is that what you are saying?

Ms Maclachlan—Class I and class II recalls are deemed to be safety related recalls. The recalls may occur at the consumer or retail level. As safety related recalls, they are required to be advertised. That is where the advertising in the national newspapers occurs. So if it is a consumer-level recall and safety related, they are required to be advertised in the daily newspapers as soon as possible.

Senator ALLISON—By consumer-level recall, do you mean those which are non prescriptive?

Ms Maclachlan—No. A consumer-level recall may be a recall that relates to a complementary medicine, an over-the-counter medicine or a prescription medicine.

Mr Slater—The difference between a prescription medicine and a complementary medicine here is that we know who has the product.
Senator ALLISON—I realise that; it is self-evident.
Mr Slater—Regarding the actual level of getting in touch with consumers, we have a much greater certainty of being able to get in touch with consumers of prescription medicines. That does not necessarily have to be through advertising. If it is on a very limited distribution from a specialist doctor, for example, we can go to those doctors that are likely to be prescribing that product and make certain that they get in touch with their patients.
Senator ALLISON—The business of major advertising is dealt with on a case-by-case basis—is that correct? There is a requirement under class I or class II?
Mr Slater—There are requirements laid down for when and what sort of advertising is necessary.
Ms Maclachlan—A safety related recall is defined under the Trade Practices Act as a recall of 'goods of a kind which will or may cause injury to any person.' Where the recall is safety related there is a legal requirement for it to be notified and of course advertised in the press.
Senator ALLISON—Can you update the committee about the charges against Jim Selim?
Mr Slater—On 26 October 2004 Pan Pharmaceuticals Ltd appeared before the Downing Centre Local Court in Sydney to answer 10 charges of manufacturing a counterfeit medicine. A Pan employee also appeared to answer 10 charges of manufacturing a counterfeit medicine. The Pan chief executive and managing director appeared to answer a charge of procuring the destruction of evidence under the Commonwealth Crimes Act. On 6 May 2005 an additional nine charges, each of manufacturing counterfeit medicines under the Therapeutic Goods Act, were brought against a Pan employee and Pan Pharmaceuticals. These charges related to the manufacture of medicines other than Travacalm in which instances of data manipulation were uncovered during the TGA investigations. On 25 May 2005, 23 charges, each under section 54 of the New South Wales Crimes Act, related to intentionally inflicting grievous bodily harm were laid at the Downing Centre Local Court against a Pan employee and Pan Pharmaceuticals.
Senator ALLISON—Those charges have been laid, but when is court action expected?

Mr Slater—The chief executive of Pan is scheduled to appear for a committal hearing at the Downing Centre Local Court on 18 to 22 July 2005. The Pan employee and Pan Pharmaceuticals will appear at the same court on 23 June 2005.
Senator ALLISON—Are the manufacturing of counterfeit medicine charges the same as falsifying documents? The TGA did indicate that that was the charge to be laid. Is that the same thing?
Mr Slater—The charges that relate to counterfeit medicines certainly do relate to that, and also the additional charges on 6 May relate to data manipulation.
Senator ALLISON—But Mr Selim has been charged only with the document destruction that related to Travacalm?
Mr Slater—That is a personal charge against Mr Selim. Pan Pharmaceuticals, as a company, has been charged with the other matters. There is a further brief of evidence on other matters that has been passed to the Director of Public Prosecutions for consideration.
Senator ALLISON—What has been the cost so far to the TGA for this action?
Mr Slater—The total cost of the investigations to date has been $1.4 million.
Senator ALLISON—Does that get cost recovered?
Mr Slater—Yes, the TGA's activities are fully cost recovered.
Senator ALLISON—Does that happen as part of the court process or will there be a charge which is levied at—
Mr Slater—In this case, these funds have been provided specifically by the government under an appropriation.
Senator ALLISON—That was not my question. Will they be recovered as part of the court process or will they be recovered in a separate process?
Mr Slater—The investigation costs and the legal costs that are associated here have been funded by the government under an appropriation. If there are fines incurred by Pan Pharmaceuticals or employees of Pan Pharmaceuticals, those fines would go to consolidated revenue; they would not come to the regulator.
Senator ALLISON—So in what sense would it be cost recovery?
Mr Slater—All of the TGA's activities are 100 per cent cost recovered, but in this instance the government has provided funds for this investigation.
Senator ALLISON—So the industry at large is not going to foot the bill?
Mr Slater—No.

Senator ALLISON—Chair, I have some questions about the trans-Tasman joint committee. Would it be possible for Senator Forshaw to put his other TGA questions now?
CHAIR—Certainly.
Senator FORSHAW—We have some on that as well. Can I follow on from the discussion you have been having with Senator Allison emanating out of the Vioxx recall. Dr McEwen, I noticed in a report that you had called for increased powers, effectively, for the TGA. I am reading from a newspaper report that refers to a *Four Corners* program on which you appeared on 11 April. It says: Dr McEwen told ABC TV on Monday he would ask for greater powers for a soon-to-be-formed trans-Tasman regulatory agency. Is that a correct report of your position?
Dr McEwen—Not absolutely correct. I think I appeared on *Four Corners* for a maximum of about three minutes and there had been about 45 minutes of interview.
Senator FORSHAW—You have done well.
Dr McEwen—Yes, perhaps. I had made the point that, up until now under the present Therapeutic Goods Act, when we registered medicines we had sometimes been of the view that further study should be done and submitted. We have in fact conditioned some registrations like that. It has always been a matter of contention as to whether we have that legal power or not, because the act could be interpreted as saying that you have to make a judgment on what you have now. That was the context in which I was putting it. I was then on leave when this discussion broke out. I think Mr Slater would want to comment about that. Thursday, 2 June 2005 Senate—*Legislation* CA 43 COMMUNITY AFFAIRS
Mr Slater—I would like to add to that answer by saying that in the trans-Tasman model that is under consideration by the government of Australia and the government of New Zealand we will be looking at the best practice models that operate in this area around the world. Dr McEwen has indicated that there are some doubts about our legislative reach. In looking at how we might improve the regulatory framework for the trans-Tasman model, we will be looking to make certain that we apply best practice models here.
Senator FORSHAW—As to the response of the parliamentary secretary, Mr Pyne, it says: Senator Pyne rejected the idea. He rejected an extension of the TGA's powers under the trans-Tasman agreement as a mistake and thought that it was unlikely to be accepted by the government because it might create difficulties and be too difficult to achieve. Is that the position?
Mr Slater—I think we would need understand the context in which and the question that the parliamentary secretary answered, and, as Dr McEwen has explained, also the context in which his abridged response to the ABC questions was televised. Dr McEwen has explained that there is some lack of clarity about the legislative reach that we have at present. There is also a question as to whether having that legislation framed in a way which reflects maybe the powers that are available to other international regulatory agencies of comparable standard should be considered in a trans-Tasman context. So he was reflecting on the possibility of better regulatory reach. I am not sure what question the parliamentary secretary was responding to, but the whole framework for the trans-Tasman agency is yet to be developed.
Senator FORSHAW—I have a quote here of what Mr Pyne said.
Ms Halton—At the end of the day we have not seen that quote and I do not know in what context the question was asked. As Mr Slater says, the government has yet to formally consider—as indeed has the New Zealand government—a final draft of the legislation or draft legislation which will provide for the trans- Tasman arrangements. The parliamentary secretary is, to my knowledge, however on the record as saying that these arrangements are not about a diminution of Australian arrangements. That is a very clear position from the Australian government. We are working in close concert with our New Zealand colleagues, and the parliamentary secretary is working closely with his New Zealand colleague. Clarifying a range of issues, including this one, obviously has to be part of the debate and negotiation prior to the finalisation of what will be draft legislation.
Senator FORSHAW—I do not think anyone is talking about a diminution. If anything, as I understand what Dr McEwen has said, there is an issue about a perceived lack of power at the moment. To paraphrase your position—and I appreciate that you may want to correct me—this could lead to increased powers, for instance, and to enforced trials by the TGA. It says here 'Senator Pyne', but it is 'Parliamentary Secretary Pyne' says: ... any extension of the TGA's powers as a consequence of the trans-Tasman agreement would need to jump the very high hurdle of not crushing initiative and being an over-reaction to a particular problem. That is from the *Financial Review* of 13 April—it is a direct quote. If that is what he said, that certainly is rejecting the proposition in the context of the trans-Tasman agreement.
Ms Halton—That quote—now that you have read it—I do not regard as being a rejection of an idea. It is simply saying that in any change that you make, or in the introduction of any legislative provision, you have to basically

ensure that all those provisions pass a fairly high test in terms of requirement. As I have said, we have not yet finalised the legislation. There is a range of issues government has yet to decide, and this would be in that category.
Senator FORSHAW—I was going to ask you about the legislation. Is the department developing legislation to deal with the potential need for more power for the TGA in the wake of these issues over the Cox-2 inhibitor?
Ms Halton—There are two separate issues here.
Senator FORSHAW—That is what I was trying to understand.
Ms Halton—There is the issue in relation to any change to the current legislation to provide for greater powers which may be implied and based on our experience recently. That is one set of potential amendments. Then there is the second question, which is: how do we frame legislation in a trans-Tasman context to provide world's best practice arrangements across the Tasman? It is probably important to distinguish what we are doing now in terms of continuing to run our business while we have the TGA, versus the arrangements we will CA 44 Senate—*Legislation* Thursday, 2 June 2005 COMMUNITY AFFAIRS put in place to run the trans-Tasman arrangements. The comment I was making about no diminution is the fundamental principle on which the trans-Tasman agency will be founded. Obviously there is a lot of legislation necessary to give that effect. But in terms of our immediate administration, there is a proposal to amend the existing legislation to strengthen the powers of the TGA.
Senator FORSHAW—Where is that at, at the moment?
Mr Slater—There is a bill that is in draft for increased penalties, which give a far greater spread of capability to the regulator to deal at the high end of—
Senator FORSHAW—That is reported on in this article as well?
Mr Slater—Yes. It also gives a much easier spread of better weighted responses at the lower end of breaches.
Senator FORSHAW—Do we have any time frame as to when that is likely to come forward?
Ms Halton—There is a draft of that bill and there is a decision that there will be a final process of discussing issues with a number of key stakeholders. Following that process and subject to the outcome of that process, that bill will proceed.
Senator FORSHAW—It is not going to be delayed because of the finalisation of the trans-Tasman agreement?
Ms Halton—Absolutely not. Never. That was the point I was making, effectively: we are continuing to run our business, including looking at the legislative issues that come from our recent experiences. That work is not in any sense deferred, delayed or altered because at the same time we are doing the trans-Tasman work.
Senator FORSHAW—But it is an issue that is on the table for the trans-Tasman agreement?
Ms Halton—It has to be, because everything—in terms of how we run a scheme—has to be debated.
Senator FORSHAW—Yes, I understand. I suppose I am just tyring to understand how you are managing the two streams, if you like, given that connection.
Ms Halton—We are juggling, basically.
Senator FORSHAW—Yes. I think Senator Allison wanted to ask some further questions about the trans- Tasman agreement. I have some on that which I can go to now.
Ms Halton—Why don't you start, Senator.
Senator FORSHAW—I do not have many. Will interest groups and stakeholders be consulted in developing the legislation for the proposed agreement?
Mr Eccles—Yes, there is a commitment by both the Australian government and the New Zealand government for a solid block of industry consultation. In the lead-up there has been significant consultation with industry groups and that will continue as well.
Senator FORSHAW—Is there a timetable for the period of consultation, because the start-up date for this legislation, I understand, is 1 July—
Mr Eccles—It is 1 July 2006, yes.
Senator FORSHAW—Yes. So do you have a timetable for completing your discussions with stakeholders?
Mr Eccles—A lot of it is dependent on when the legislation is finalised. Australian parties and New Zealand parties are exchanging views and in some instances exchanging pieces of drafted legislation. We have got the New Zealand election coming up and that of course is going to play a role in determining the time frame to go out to industry. But we are hopeful that we will be going out to industry in the second half of this calendar year.
Senator FORSHAW—And you would be going out to industry with draft legislation?
Mr Eccles—Exactly. But there has been a lot of consultation in the lead-up to now, so I think it would be fair to say that they are very aware of the nature of the scheme that is being developed.
Senator FORSHAW—Is the start-up date of 1 July still feasible? Are you still confident you can meet that?

Mr Eccles—It is certainly technically feasible in Australia. Sorry?
Senator FORSHAW—Are you confident you can still meet that?
Mr Eccles—Confident?
Thursday, 2 June 2005 Senate—*Legislation* CA 45COMMUNITY AFFAIRS
Senator FORSHAW—I know that the situation might change in the Senate after 1 July and that might hasten the passage of the legislation, but—
Ms Halton—It is our expectation that that is the commencement date. We do not, regrettably, have a crystal ball, but that is the date to which everybody on both sides of the Tasman is working.
Senator FORSHAW—But even if the legislation were to be passed quickly—the start-up date is not just dependent on that, is it?
Mr Eccles—No. The process really would be to have legislation drafted to a point of agreement between Australia and New Zealand, industry engagement, discussion with industry and introduction in relevant houses here and over there, and then the rules would need to be introduced as disallowable instruments.
Senator FORSHAW—If I can go off trans-Tasman for a minute and go to the Cox-2 inhibitors. This may have been covered by Senator Allison—I may have missed it—but is the TGA undertaking a review of all the Cox-2 inhibitors?
Dr McEwen—The answer is yes, that review was undertaken quite promptly after the withdrawal of Vioxx. There are two other Cox-2 inhibitors that are marketed in Australia. One is celecoxib, or Celebrex; the other is meloxicam. As a side issue, there has always been some debate as to whether meloxicam is or is not a Cox-2 inhibitor—but it is certainly close to them. There was also another marketed Cox-2 inhibitor that is very different in that it was marketed for pain relief at the time of anaesthesia and not taken for arthritis, osteoarthritis or rheumatoid arthritis. It is in rather a different category, but it was reviewed. From memory, there were two other Cox-2 inhibitors that were yet to be marketed in Australia. All of those were reviewed. In each instance the sponsor was invited to submit all the data that they had that might update us on the risk of heart attacks in people taking these drugs. They were considered by the Australian Drug Evaluation Committee in February, and actions have been taken. They vary through each of those Cox-2 inhibitors but, at the very least, each of them has had very clear warning statements being added to the product information. In a couple of instances, or for some uses, the registrations have been withdrawn.
Senator FORSHAW—So the review has been completed?
Dr McEwen—In essence it has been completed, yes.
Senator FORSHAW—Is there going to be some report released on that? Either publicly or to—
Dr McEwen—There have been media statements that we could get from the web site for you.
Senator FORSHAW—I am often told never to rely on the media.
Dr McEwen—No, this is the TGA's web site.
Senator FORSHAW—Okay.
Dr McEwen—There have been statements as to the outcomes of those, as a starting point for you. We can provide those.
Senator FORSHAW—We can check that, but is there to be some specific report produced and publicised either generally or to the industry?
Dr Hunt—The issue of the review is that a large amount of the data that was considered as part of the review was regarded as commercial-in-confidence by the people who submitted it. They have put limitations on the material that we can release into the public domain. The statements that have been placed on the TGA web site are an attempt to summarise the outcome of the consideration of the issue by the Australian Drug Evaluation Committee and the TGA without breaching that commercial confidentiality.
Senator FORSHAW—Whatever you put on the web site is the sum total of what would be made publicly available arising from the review?
Dr Hunt—That is the main publicly available information, yes.
Senator FORSHAW—I am not sure if Senator Allison wants to carry on with trans-Tasman, but I want to ask a couple questions about the free trade agreement as it affects the area of complementary medicines. Is it the case that the TGA now requires that every new product listed on the register must include a statement that patent searches have been conducted? Is that correct?
Mr Slater—The TGA legislation requires that where a certificate has to be provided, either there is no patent over the product or, if there is, the applicant has advised the patent holder as required under the free trade agreement. CA 46 Senate—*Legislation* Thursday, 2 June 2005 COMMUNITY AFFAIRS
Senator FORSHAW—Is what I said inconsistent with what you have just said?

Mr Slater—They have an option. They can just advise us that they have advised the patent holders involved, or they can give us a certificate that says there is no patent over the product in question.
Senator FORSHAW—It means they will have to have done a search to ensure that what they tell you is incorrect.
Mr Slater—They have to give us advice as to the existing patent holder obligations they have under patent law, whether there are any patents involved there and, if there are, whether they would advise the patent holder.
Senator FORSHAW—As I understand it, the manufacturers of complementary medicines are claiming that they are particularly disadvantaged by these requirements to have this statement. Are you aware of that?
Mr Slater—Yes. They are certainly concerned that, generally speaking, their products would not fall into the category of where a patent is involved. We agreed with them about that, but they are raising concerns about being certain whether any patents exist for their products. There is a considerable amount of work involved in searching patent records.
Senator FORSHAW—That is what I was getting to. Would that seem to be an unintended consequence of the FTA? Was anyone aware of this at the time of the negotiations?
Mr Slater—The FTA was to ensure that Australia's administration of patent obligations was rigorous on the patent holding sector and some classes of registered non-prescription medicines. The application of patents in the area of complementary medicines is reasonably unusual. There are some over proprietary ingredients and over some new developments where a company has patented those activities. Those patent requirements should generally be well known, but there is this obligation to provide a certificate and that has caused some concern to the complementary medicines industry.
Senator FORSHAW—As the TGA, you are aware of their concerns. Is there any action being considered to try to alleviate them, or is there anything possible? As I understand it, the requirement is that every new product must include a statement or a provision of this advice about—
Ms Halton—You are accurately reflecting the requirements of the legislation. I can say that, from a policy perspective, this issue has been drawn to the minister's attention. You are quite right in terms of the issues that have been raised. He is currently considering the matter.
Senator FORSHAW—It is before the minister?
Ms Halton—It is before the minister.
Senator FORSHAW—And the department has provided advice to the minister?
Ms Halton—Yes, that is right.
Senator FORSHAW—Senator Allison, you had some questions on the trans-Tasman agreement you wanted to pursue.
Senator ALLISON—I am at something of a disadvantage if you have already asked questions, because I—
Senator FORSHAW—I only asked a couple of questions with regard to who was being consulted in the development of the agreement and what the timetable was for the negotiations and the legislation.
Ms Halton—While Senator Allison is finding her place, I will add something to the record. Senator Allison, you asked about the accidental/incidental exemption provisions and whether we had received any matters we had investigated. The answer is that, in the last 12 months, two matters have been investigated.
Senator ALLISON—Could I ask about the joint expert advisory committee recently announced to oversee the establishment of standards for therapeutic products under the new trans-Tasman joint regulatory agency. Is it the case that only two of the total of 23 members of that committee will have any expertise in complementary medicines?
Mr Slater—I would need to go back and research the detailed CVs of those members to be absolutely certain of that, but without doubt there are two members who have been appointed for their expertise in complementary medicines.
Senator ALLISON—Are those members also associated with pharmaceutical companies?
Mr Slater—We would have to go back and have a look at the membership. Thursday, 2 June 2005 Senate—*Legislation* CA 47 COMMUNITY AFFAIRS
Senator ALLISON—If you would. What was the selection process for that expert advisory committee?
Mr Slater—The Therapeutic Goods Committee, appointed by the minister, is an existing statutory committee that the TGA uses to establish standards. It sets the standards for the regulator to apply to therapeutic goods manufactured in or imported into Australia. The new standards committee is an evolution of that Therapeutic Goods Committee into a trans-Tasman committee setting standards. The two governments considered the range of expertise available for membership of that committee, and that committee was decided by the interim ministerial council oversighting the establishment of the joint regulatory scheme.

Senator ALLISON—By ‘evolution’, do you mean that the group on the old committee was just put onto the new committee?
Mr Slater—No. The work that the Therapeutic Goods Committee has been doing to date will in the future be taken up by this new standards committee. There was an expertise set up under the Therapeutic Goods Committee such that those individuals would have been considered by ministers on both sides of the Tasman as to whether they should be appointed to the new committee. So there are some members of the Therapeutic Goods Committee who have taken their expertise onto the new committee.
Senator ALLISON—How many?
Mr Slater—I would have to take it on notice to work out how many there are.
Ms Cobbold—Certainly there are a number, but a small number—by no means all of the existing members of the Therapeutic Goods Committee.
Senator ALLISON—But you are not able to tell us how many?
Ms Cobbold—No.
Senator ALLISON—Is it roughly half, many more than half or generally in the order of half?
Ms Cobbold—No, it would be less. Probably of that order, but probably less, I think. The standards committee has a core membership and then a much larger group of associate members, if you like, with particular expertise who will be drawn on for the development of particular kinds of standards.
Senator ALLISON—And that will not happen with the new joint committee?
Ms Cobbold—I am talking about the new joint committee. In drawing up that wider list of expertise, we have gone more broadly in both Australia and New Zealand to come up with possible members for ministers to consider.
Senator ALLISON—So there is a list of 23 members and then there is a wider list of members?
Ms Cobbold—No, the big list of 23 is the core members plus the associate members.
Senator ALLISON—How many are on the current list?
Mr Slater—We would need to take that on notice, as we said.
Senator ALLISON—No, how many people are on the statutory committee?
Ms Cobbold—On the Therapeutic Goods Committee?
Senator ALLISON—Yes.
Ms Cobbold—I am advised by the colleague who is responsible for the current Therapeutic Goods Committee that there are up to 10.
Senator ALLISON—Do we have half the membership? Are the 23 members all ours, or are half of those New Zealand’s?
Ms Cobbold—No, I do not think it is anything like half, but I would have to take it on notice. We will give you the list of names and we will indicate which ones are currently on the Therapeutic Goods Committee.
Mr Slater—I think it is important that the context here is that therapeutic goods are not just medicines; they are medical devices. Standards are also set for blood and blood products and for medical devices including products such as tampons, so there are a very wide range of standards that apply to goods that are produced here.
Senator ALLISON—So is it possible to get a full list of members and their qualifications?
Mr Slater—Yes.
Senator ALLISON—Was the complementary health sector consulted in these decisions?

Mr Slater—Yes.
Senator ALLISON—Who was consulted?
Mr Slater—The Complementary Healthcare Council and its equivalent in New Zealand, through the New Zealand government. It was a decision of the New Zealand government as to whom they consulted.
Senator ALLISON—Did they make specific recommendations or did you just say, ‘Here’s the list. What do you think?’
Ms Cobbold—They made specific suggestions.
Senator ALLISON—And were they adopted?
Ms Cobbold—It is a while ago now. I cannot remember. I am pretty sure they were. I am confident that members of the committee with expertise in manufacture of particular kinds of products, which was needed for the committee, were supported by the relevant sectors, from which that expertise could be drawn.

Senator ALLISON—It would be useful if you could tell us what the recommendations of the Complementary Healthcare Council of Australia were—I guess we can ask them that ourselves—whether they were taken up; if not, why not?
Mr Slater—We will be able to confirm whether they were taken up.
Senator ALLISON—What about a consumer representative on that body?
Ms Cobbold—There is a consumer representative on the body.
Senator ALLISON—How is that representative chosen?
Ms Cobbold—Nominations were sought from Australian and New Zealand organisations and the ministers made a selection.
Senator ALLISON—Is the representative a New Zealander or an Australian?
Ms Cobbold—A New Zealander.
Senator ALLISON—How many were there on the list of possibles?
Ms Cobbold—My recollection is that, for the consumer representative, there were three or four. As I say, it is a while ago. I should check that and confirm for you.
Senator ALLISON—I am sorry, I do have that list of members. I think you might have provided it to my office. I apologise for that.
Ms Cobbold—I thought it did indicate which ones were current members of the Therapeutic Goods Committee. My recollection of the list, from when we prepared it some time ago, is that we asterisked them or something like that. It is listed in their list of expertise that they current members of the Therapeutic Goods Committee.
Senator ALLISON—It is indeed. I apologise.
Ms Cobbold—You have the list. I am afraid that I have not got a copy with me.
Senator ALLISON—I move now to a slightly different topic. Are you able to speak about the review of the consultative mechanisms of the Therapeutic Goods Administration?
Mr Slater—Yes.
Senator ALLISON—When will the report of that review be made publicly available?
Mr Slater—I understand that it is likely to be made available in the very near term—and that means in the next day or so. I am aware that you have an outstanding question on notice on this report.
Senator ALLISON—When was the review started?
Mr Slater—The review commenced in June 2003.
Senator ALLISON—It has taken a long time.
Mr Slater—It reported in July-August 2004. We released it to industry stakeholders in August 2004. We have taken it through successive rounds of consultation with them. There were formal meetings in October 2004 and in May 2005 to discuss responses to the consultants views. We also made changes to the consultative arrangements as a result of the October discussions, taking those through the parliamentary secretary form approval.

Senator ALLISON—Will that report include recommendations?
Mr Slater—The consultant's report is the consultant's views. The consultant has drawn some conclusions and made some recommendations.
Senator ALLISON—Is that on the minister's desk at present?
Mr Slater—Yes, the minister is about to make a decision to release that report publicly, and also to answer your question.
Senator ALLISON—That will be in the next day or so?
Mr Slater—Yes.
Senator FORSHAW—Where does the Office of the Gene Technology Regulator fit in here?
Mr Slater—It fits within the TGA group of regulators. We have officers here.
Senator FORSHAW—Can I ask you about Bt10 corn?
Mr Slater—You can.