STANDING COMMITTEE ON
UNIFORM LEGISLATION AND STATUTES REVIEW

MEDICINES, POISONS AND
THERAPEUTIC GOODS BILL 2013

TRANSCRIPT OF EVIDENCE
TAKEN AT PERTH
MONDAY, 28 OCTOBER 2013

Members

Hon Kate Doust (Chair)
Hon Brian Ellis (Deputy Chair)
Hon Mark Lewis
Hon Amber-Jade Sanderson

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Hearing commenced at 1.18 pm

KEEN, MR NEIL
Chief Pharmacist, Pharmaceutical Services Branch, Department of Health, examined:

CARPENTER, MS JANE
Manager, Legislation and Licensing, Pharmaceutical Services Branch, Department of Health, examined:

DANIELS, MS ROBYN
Senior Solicitor, Department of Health, examined:

The CHAIR: On behalf of the committee, I welcome you to our hearing today. This is our first real discussion about the Medicines, Poisons and Therapeutic Goods Bill 2013. I will introduce the members of the committee. We have Hon Amber-Jade Sanderson, Hon Brian Ellis, Hon Mark Lewis and Linda Murdoch, our research officer. I am Hon Kate Doust, the Chair.

Before we start, I have a few formalities to read through, so bear with me if you would. Today we are not going to ask you to take an oath or affirmation. You would have signed a document entitled "Information for Witnesses". Have each of you read and understood it and signed it?

The Witnesses: Yes.

The CHAIR: These proceedings are being record by Hansard. Once the hearing is over the committee will provide you with a transcript of your evidence. To assist both the committee and Hansard, we ask that you quote the full titles of any documents that you refer to during the hearing for the record. Please be aware of the microphones and talk into them. Ensure that you do not cover them up with papers or make noise near them. I also remind you that the transcript will be a matter for the public record and if for some reason you wish to make a confidential statement during today's proceedings, you should request that the evidence be taken in closed session. If the committee grants your request, any public and media in attendance will be excluded from the hearing—I do not think that is an issue today. Please note that until such time as the transcript of your public evidence is finalised it should not be made public. I advise you that publication or disclosure of the uncorrected transcript of evidence may constitute a contempt of Parliament and may mean that the material published or disclosed is not subject to parliamentary privilege. So that is the warm opening we have for you today; we have to do that.

The committee has a series of questions, and I note that we have just today received a response to those questions; but would one of you like to make an opening statement to the committee about the bill? If you do not want to do that, we will go straight into questions.

Mr Keen: I have one prepared if that is acceptable.

The CHAIR: Excellent.

Mr Keen: Thank you very much. To start, medicines and poisons are not ordinary items of commerce. They provide significant benefits to the community and individuals, but they are inherently dangerous and cause significant harm if misused. Even with the existing well-established controls, there are approximately a quarter of a million calls to state poisons information centres each year. In all states and territories of Australia, medicines and poisons are restricted substances and not freely available to the general public. At present, poisons are regulated by the Poisons Act 1964. This act is 49 years old, is seen as outdated, inflexible and difficult to navigate and requires update to meet changes to business, workforce and chemicals use patterns in the community.

[1.20 pm]

The bill is intended to provide an overarching framework for the efficient and effective oversight and guidance for persons that handle medicines and poisons. In part 1, the bill classifies medicines and poisons according to the danger they pose or the level of risk to the public. Schedule 2 is pharmacy-only medicines; schedule 3 is pharmacist-only medicines; schedule 4 is prescription medicines; schedule 5 is poison–caution; schedule 6 is poison; schedule 7 is dangerous poison; schedule 8 is controlled drug; and schedule 9 is prohibited drugs. These schedules are derived from the Standard for the Uniform Scheduling of Drugs and Poisons. The standards are maintained by the commonwealth and adopted by reference in each jurisdiction. This provides national consistency, such that drugs such as morphine are not treated differently in different states. This also provides for uniform approaches to packaging and labelling. These standards ensure public safety, such as with label directions in case of poisoning; increase efficiency for businesses trading nationally; and reduce confusion for Australian consumers. The authority to sell or supply medicines and poisons is contained in drugs and poisons legislation in each state and territory. The level of control and authority to sell or supply is dependent upon the classification of a particular medicine or poison; that is, the schedules.

In part 3 of the bill, the authority of the health professional to supply, administer or prescribe a medicine is outlined. The health professional is mainly a health practitioner registered under the Health Practitioner Regulation National Law. The competence and credentials of an individual practitioner and the scope of practice of a particular professional group are uniformly treated under this nationally consistent legislation.

In part 4, the bill allows for persons to sell, supply or use a poison when appropriately licensed or permitted by the CEO of Health. Part 4 requires persons to be suitably qualified, have sufficient resources and be fit and proper persons to safely manage dangerous or toxic chemicals that are required for both domestic and industrial applications. Any licensed or permitted person has obligations for the responsible, safe and secure storage, supply, disposal, record keeping and advertising of poisons. The CEO must keep a register of all of these licensed and permitted persons under the bill. Part 7 of the bill deals with aspects of drugs of addiction that are regulated under this bill.

Therapeutic goods are broadly defined as products for use in humans to prevent, diagnose, cure or alleviate a disease, ailment, defect or injury. Medicines are a major, important and high-risk type of therapeutic good. Therapeutic goods also include sunscreens, diagnostic tests, imaging equipment such as X-rays, medical consumables such as bandages, medical devices such as syringes, human tissues, blood products, and so on. Historically, these goods were regulated by states and territories. In the 1980s and 1990s, with increasing technological sophistication and range of goods, this responsibility was passed to the commonwealth. These are now regulated by the commonwealth Therapeutic Goods Act, which is administered by the Therapeutic Goods Administration. This national legislation ensures that health consumers are not exposed to untested, unsafe, ineffective or substandard products. It also prevents false or misleading claims or advertising with respect to the health benefits of therapeutic goods.

There are also a number of notable and relatively regular instances of failure of therapeutic goods. These affect large numbers of consumers and have dramatic, even life-threatening, effects for individuals. They also incur large costs to government and the health sector in rectification of the health effects they cause. While most therapeutic goods are produced now by larger businesses and traded nationally or internationally, such as by big pharma companies, there are still small traders and entrepreneurs seeking to manufacture and trade therapeutic goods. This commonwealth law does not extend to sole traders operating within a single state. The failing of this national law within an individual state means that Western Australians are potentially not protected from harmful therapeutic goods. Each year, there is a small number of therapeutic goods identified and produced within WA that make unsubstantiated claims. The government and the department have no specific powers to make a supplier rescind misleading claims or to cease trading of a dangerous good. These

are usually traditional or complementary medicines that contain scheduled poisons or unscheduled chemical substances.

In 2005, COAG agreed that the states and territories would adopt commonwealth therapeutic goods laws to close these loopholes. These laws have so far been adopted by New South Wales, Victoria, Tasmania, South Australia and the Australian Capital Territory. In the Northern Territory, a law has been assented to but not enacted, and Queensland advises that it is currently considering adoption in the rewrite of its poisons legislation.

Part 6 of the bill proposes to adopt these commonwealth laws as laws of Western Australia. Adoption by reference is an efficient method of closing the loophole. In 1994, Victoria enacted mirror legislation for this purpose. In 2010, Victoria changed to adopt the legislation by reference. The Victorian drugs and poisons regulation unit has advised that constant and substantial changes to the therapeutic goods landscape and the commonwealth law lead to unworkable legislative drift over time.

A similar model also exists for veterinary and agricultural medicines and poisons. The commonwealth Agvet Code that governs the use of these substances by vets, farmers, pesticide operators and so on is adopted by Western Australia in the Agricultural and Veterinary Chemicals (Western Australia) Act 1995. This code is administered by the APVMA, which might be considered the equivalent to the TGA for animal products.

The replication of this legislation—that is, the Therapeutic Goods Act—would have significant resource implications for the Western Australian government to administer and manage in a similar scheme for a very small number of products each year. This would include very large compliance and legal costs. In addition, much of the specific TGA expertise is not available within WA and could not be easily acquired outside the TGA. It is likely that there would be an increased cost to business in making therapeutic goods comply with a less efficient WA regulatory scheme as opposed to that of the TGA. This would translate to increased costs to consumers of these products.

In summary, part 6 of the bill seeks to close a loophole for sole traders operating within Western Australia relating to therapeutic goods. It proposes to adopt by reference commonwealth law on therapeutic goods, which is considered to be the most efficient mechanism for doing so.

Thank you.

[1.30 pm]

The CHAIR: Thank you for that. That is a very good overview. Just picking up on one issue out of that, you talked about how difficult it is in Western Australia when there are complaints about the failure of certain therapeutic goods and there is not any capacity to follow through on that. So, consumer protection legislation does not apply there in terms of people pursuing action in those cases?

Mr Keen: I am not sure I am wholly qualified to comment; however, I could give you what I believe my opinion is. It is very easy for a sole trader to reformulate, repackage or relabel a product, and I believe consumer protection can only regulate the name of the product, not actually the contents.

Ms Carpenter: Also, if I could say something about that, the consumer law regulates those supplying only. It is about selling to people only, and it stops at that point.

The CHAIR: It is not about manufacturing.

Ms Carpenter: Exactly. It is a bit limited in what it can do.

Hon MARK LEWIS: In the opening comments you made, you gave, I guess, the benefits of doing this. Are there risks, and what are the threats to WA? This committee is particularly worried about sovereignty. You did not outline any risks or threats within that opening comment. Do you see any?

Ms Daniels: Black salve, and you two could perhaps explain that.

Ms Carpenter: Can I just clarify, do you mean —

Ms Daniels: Risk if we do not adopt.

Ms Carpenter: — risk if we do not adopt or risk if we do adopt?

Hon MARK LEWIS: Yes.

The CHAIR: It is potentially both.

Hon MARK LEWIS: I think you just gave one side of the story. I want to know whether you see any risks or threats.

Mr Keen: Maybe I will start with risks if we do not adopt. If we do not adopt, we maintain the current situation where we cannot regulate.

Hon MARK LEWIS: I think you have covered them, yes. And if we do adopt?

Mr Keen: If we wrote it ourselves, it would be very costly and expensive. In adopting the commonwealth law, yes, I suppose, theoretically the commonwealth law does change from time to time. It is very long and very complicated. It is also quite costly for manufacturers of goods. There are two situations. High-risk therapeutic goods go through a very rigorous process which is quite costly. However, if you are making something that is high risk, it is usually also high cost and you also need very large facilities and a reasonable amount of resource. So, for those manufacturers, it is not usually a difficulty. If you are much smaller, of course, then it might be more costly for you to produce something and there might be certain competition issues. For those low-risk things—generally, they are low risk—it is actually less costly to go through the TGA, but it would be less costly to use the TGA regime than it would be to use an equivalent WA regime, which would be probably more costly for us to actually institute.

The CHAIR: We might come back and talk about those sorts of issues. One of the things we are interested in is the history behind this piece of legislation, where it started and how we got to this point. I understand there have been some issues around providing documents and copies of the agreement that are meant to underpin this piece of legislation. You might explain to us firstly the history and then we will have the discussion about the documents.

Ms Carpenter: The history actually started 10 or 12 years ago. There was a review known as the Galbally review, which was a review of all poisons and therapeutic goods legislation in states and territories by a lady by the name of Rhonda Galbally under the national competition policy framework. That review was published in 2001, and recommendation 23 of that review was that all states and territories adopt the commonwealth legislation to cover the loophole that existed at that stage in every state—I think, even probably Victoria; New South Wales might have, but do not quote me on that—that allowed sole traders trading entirely within one jurisdiction to escape any regulation by the commonwealth. That was recommendation 23. An AHMAC subcommittee then looked at all the different recommendations from the Galbally review, and their report came out in April 2003. It was referred to COAG and then in June 2005, COAG unanimously agreed to all the recommendations of the AHMAC subcommittee and their recommendation for Galbally's recommendation 23 was that it was adopted.

The CHAIR: Can we stop at that point? I understand that that was an out-of-session COAG meeting.

Ms Daniels: Correct.

The CHAIR: Can you explain how that works? How did they go about signing off on it if it was out of session?

Ms Daniels: We cannot find anything except for the document that you have in your —

The CHAIR: The Mark Vaile letter?

Ms Daniels: The Mark Vaile letter. That letter was sent to, as you can see, Carr, but they gave us the envelope that it had come in in relation to it. That is all they can give us at the moment. I have asked the Department of the Premier and Cabinet's intergovernmental relations to follow up with the COAG committee to try to find copies, if there was an agreement. I am not completely familiar with the out-of-session process, except in the health space. There are often recommendations and documents that are agreed to out of session by the minister for, in this case, health. So those documents are circulated and ministers are asked to respond to those and that is how it is done. As to COAG, I would predict that it would be the same way, but I do not actually know that. But we will follow up with the COAG secretariat in Canberra and give you whatever we can find in relation to that.

The CHAIR: That would be very much appreciated. It makes our job as a committee difficult if we cannot see that document. Do you have any idea of time frames in terms of response?

Ms Daniels: I am sorry; no, I do not have any idea of time frame. I did ask specifically today; I sent an email to them. I will follow up. If I can get a time frame, I will feed it back to Linda.

The CHAIR: That will be appreciated.

Ms Daniels: And for the record, attachment 2 is a copy of the final report part A of the review of drugs, poisons and controlled substances legislation. The last page of that section has the specific recommendation in relation to the adoption. Attachment 3 is the Australian Health Ministers' Advisory Council working party response to the Galbally report.

Ms Carpenter: And that is the thing that COAG agreed to in June 2005—the AHMAC working group recommendations.

Hon MARK LEWIS: But only to recommendation 23.

Ms Carpenter: No. We have not given you the whole document. We have given you only recommendation 23 because that is the only one that was applicable to adoption of therapeutic goods laws. All the other recommendations related to other aspects of the therapeutic goods laws.

[1.40 pm]

Hon MARK LEWIS: By inference there is no intergovernmental agreement.

Ms Carpenter: There is an agreement by COAG. We do not have the documentary evidence of that.

Ms Daniels: To the specific question "Do we have an intergovernmental agreement, a document that stands on its own as an intergovernmental agreement?", we are not in possession of that.

The CHAIR: Do we know that one exists?

Ms Daniels: That again I cannot answer.

The CHAIR: That will be interesting; we look forward to your response. Now, one of the questions—I know you have already provided some of this information, but we wanted to have discussion around that part 6 of the bill. If you could actually take us back through and talk about part 6, and I think we have probably got some questions about how that part operates.

Ms Daniels: So you want us to expand on what Neil said about part 6?

The CHAIR: Yes, I think so.

Ms Daniels: With your permission, I think if we can do that as the three of us.

The CHAIR: Sure.

Ms Daniels: In constructing the bill, we had the choice of creating within the bill the 577 pages of the Therapeutic Goods Act or adopting by reference the therapeutic goods for the specific small

number of people in this state. What Neil talked about was the Therapeutic Goods Act covering corporations in their entirety.

The CHAIR: Can you give us a couple of examples of those types of corporations in Western Australia?

Ms Carpenter: It would be big pharmaceutical manufacturers.

The CHAIR: So Pfizer?

Ms Carpenter: Yes.

The CHAIR: What about companies like Genzyme?

Ms Daniels: Any company that is a corporation. How the commonwealth can do this is they are using the Corporations Act for regulating corporations. The constitution does not allow the commonwealth to regulate sole traders, a natural person. Once they become a corporation, once the three of us joined together and became a corporation, then the power of the Therapeutic Goods Act comes into play in whatever we manufacture, but while you are a lone person, a natural person, who produces a product—I said earlier about black salve. Last year—and this is not legal, but these people can comment—or earlier this year, a person produced a substance called black salve, which was supposedly a breast cancer —

Ms Carpenter: It is touted as a cancer cure, particularly for breast cancer, and it is applied to the skin, but it has in it substances that are corrosive. There have been consumers hurt by it in WA where they have actually had scarring and wounds to their skin and there is absolutely no scientific proof that it has any benefit in treating cancer, but it is still advertised as a cancer cure. Unless it has in it substances that are currently covered by our Poisons Act—so what we called scheduled substances, which Neil described earlier—we have absolutely no power to do anything about it under our current legislation.

The CHAIR: If they claim it to be like a herbal-based product?

Ms Daniels: Yes, but it has to be an individual who does it, so if I cook it up in my laundry or bathroom and I say this will cure baldness —

Ms Carpenter: And maybe sell it at the local farmers' market.

Mr Keen: In the case of black salve, we did speak with the Therapeutic Goods Administration, who advised that they could not do anything and there really was no avenue for us to do anything either. The department took what is a fairly unusual step and issued a media alert to say to people, "Please, be very careful." The issue—and there were several—is that, firstly, they were promoting it as a cancer cure; secondly, there is very good evidence that it does not cure cancer but it does actually harm people and prolongs, I suppose, the time it takes for them to seek appropriate help, in which case their treatment is much more difficult; and, thirdly, there were people who suffered quite nasty corrosive burns because, as you can imagine, you are putting this actually onto the breast tissue itself. The interaction with the manufacturer, I suppose, was to ask them to withdraw their claim and also to withdraw their product to which they refused. Luckily, there was a scheduled substance in it, which allowed us to take some action, but it does not stop them reformulating to remove that and still promote it as a cancer cure. There were about three ingredients, I believe, and two of those are not regulated, so I believe they have reformulated it. You asked earlier why consumer protection could not do something. They possibly could, but the other aspect of the therapeutic goods act is that it allows you if you have appropriate evidence and something that is worthwhile and should be available for consumers to have that positively assessed as effective and then come under an umbrella that allows you to use the standardised packaging and labelling and, in particular, a way of stamping something to say to a consumer, "Look, this has been assessed and it is okay." Once you have got that, it can go onto the shelves and be sold with relative confidence. I think that case in a nutshell really explains what the problem is.

Ms Daniels: I repeat, again, that it is for a small number of persons who may produce the substances as an individual, as a natural person. The moment you form a corporation, the Therapeutic Goods Act can come into play.

The CHAIR: Thank you for that. One of the issues that we are always interested in with these types of bills is: how does the state interact with the commonwealth and what capacity does the state have to have a say in any changes that are made by the commonwealth? I know that we have another question here that talks about the functions and powers of the WA Minister for Health in relation to that part 6. I know that part of your answer says that the Minister for Health has no direct functions in relation to part 6. That causes us some concern about the capacity of the commonwealth to go off and make a whole range of decisions without any direct involvement, if you like, or engagement by either the state minister or any reference back to the state Parliament.

Ms Daniels: I am responsible for that particular response and the way I have interpreted it is part 6 is primarily about the adoption of the commonwealth Therapeutic Goods Act. Does the Minister for Health have a function within that? I suppose, if I think about it more clearly, he has a function in that he can write regulation to counteract the—but I interpret that as he has powers to do that, not a function. That is how I have interpreted that.

The functions, as I have outlined under point 8, is, in the first instance, what this section does is almost import the text of the Therapeutic Goods Act into our bill, but it allows the minister to change that text if he or she so chooses. So, that is clause 78(4). Clause 82(2)—the minister has the power to by regulation amend, change, modify the commonwealth administrative law. Clause 93—by regulation to override, modify or delete specific enactments or provisions, including retrospectivity. My explanation of that is that Neil talked about how the Victorian government had mirror legislation and then changed to adopting by reference, and the reason that they did that was because the Therapeutic Goods Act is constantly changing. Medicines are constantly changing. Therapeutic goods are constantly changing.

[1.50 pm]

If there were some change in the Therapeutic Goods Act that we looked at in retrospect and thought, "Oh, my goodness, we don't actually want that to apply", and poor natural person Fred has been impacted on by that, we can retrospectively change that circumstance. That is what clause 92 does. Clause 148 is a general regulation-making power. That is not in part 6. Clause 163, the minister—again not in part 6, further in the bill—has a specific power to exempt certain therapeutic goods from the requirements of the Therapeutic Goods Law (WA).

Mr Keen: If I might make a quick statement; the commonwealth law does change from time to time, as Robyn has alluded to, because the actual goods themselves change. By way of illustration, over the past decade, an example might be tissue-derived products, which are not organs; they might be things like bone, which is harvested from a human, repackaged and treated—processed—and then used as maybe a bone-filling matrix in another individual. Clearly, that needs to be a high-quality product, so how do you harvest the original material? How do you treat it to remove all sorts of things like HIV, hepatitis or even mad cow disease? The standard expected of that should really be the same for every consumer in Australia. There should not be a lower standard for an Australian or someone operating within Australia. The point is that new sections of the commonwealth act were produced to deal with those particular types of new products and there probably always will be. It is a very complex area and would be very difficult for us to keep up with and replicate. As Robyn suggested, even if they did consult with us over the changes, if we did not like them, there is the opportunity or the power here to actually either remove them, exempt them, change them or apply a different standard.

Ms Daniels: Something else we have not spoken about is that in my definition—Neil also, I think, did the same thing—of the very small group of natural persons that we are targeting here, they have to operate only in this state as well. If they cross a border, they again get picked up by the

Corporations Act and the Therapeutic Goods Act. Neil reminded me of it when he said people in Western Australia need the same standards as everyone else. It is just within this state that we are trying to use this legislation—natural persons who produce, manufacture or trade therapeutic goods.

Mr Keen: In the case, for example, of bone tissue, it is very expensive and very specialised to get a big enough market and to connect with the people willing to pay the high prices you would need to trade nationally. It is unlikely we are talking about those sorts of products. We are more likely to be talking about things you can easily make yourselves, sourcing chemicals from China or overseas, cook up fairly easily and, these days, package and label fairly professionally, but really, without doing your homework on whether it works, without having, I suppose, a really clean sterile environment with all the checks and balances, quarantine, analysis and testing of your product; that type of thing. It is likely to be much smaller operators and not for those very high–risk materials but the things that could cause a problem such as black salve.

Hon MARK LEWIS: On the veterinary side or agriculture, WA can be quite unique in that it may have or may not have a disease that is over east. I am just checking that clause 148 will give WA the power to allow or disallow a certain chemical or therapeutic good that may not be on the national schedule.

Ms Carpenter: Can we be clear that part 6 is about adopting the Therapeutic Goods Law, which applies only to human therapeutic goods.

Hon MARK LEWIS: Only human; right.

Ms Carpenter: Yes.

Hon MARK LEWIS: Does the bill not handle —

Ms Carpenter: The bill as a whole also handles veterinary medicines where they contain a substance in the poison schedules. It would not handle those medicines if they did not contain a substance in the poison schedules. That would currently be already handled under the Agvet Code, which is already adopted by reference into agricultural legislation.

Hon MARK LEWIS: But that reference is a national schedule, not particularly WA?

Mr Keen: We can indeed answer the question and are very happy to do so, but it is not relevant to part 6. If you want us to, the easiest way to explain it is that in part 1, which provides the schedules, they are taken from the national standard, so they are consistent nationally.

Ms Daniels: Commonwealth standard.

Hon MARK LEWIS: Commonwealth standard. However, there is the ability for the minister to recommend that a substance be identified in the regulations any way the minister sees fit. If WA had a particular item—an item that comes to mind is kava, which is restricted here and not restricted in other states—the same could happen for an agricultural chemical, absolutely.

Ms Carpenter: That is exactly the same scenario as in the current legislation and there was an instance a few years ago when the minister did actually give more time for WA producers of stock feeds to move over to not using one of the antibiotics when it had been scheduled nationally into S4. We left it out of S4 for a little bit longer for a transition time in WA. That is exactly the same as it is now and it has been used.

Ms Daniels: Again on the specific question, clause 148 is outside part 6, so it is a general regulating power for the minister across the whole act.

Hon MARK LEWIS: That is the point I was trying to get at.

Hon BRIAN ELLIS: On the answer then to question 6, bearing in mind we have only just seen your responses, initially I thought the powers were with the commonwealth minister but the state minister can disallow?

Ms Daniels: Correct.

The CHAIR: The last question you provided an answer to is about the five-year review. From that I take it that the commonwealth minister would conduct the review, or is the state minister?

Ms Daniels: No, it would be the state minister. The review would be of our act and how the interaction with the commonwealth Therapeutic Goods Act—part 6 and the small group of people it may deal with in that five-year period—did work or did not work from the state's point of view.

The CHAIR: I have not had the chance to look at that part. Is there a requirement to provide that information back to the commonwealth?

Ms Daniels: No. Sorry Linda. When Linda asked me this question, I thought, "Oh, I'd never thought of it like that." This is a standard insert for bills from the health point of view that in every five years there is a clause that we will review the act in five years to see whether it is effective.

[2.00 pm]

Mr Keen: The review is of all parts of the act: are they working? Part 6 is included in that review. I expect that we will look to our records to see how many instances there have been of Western Australians affected by this, what the TGA have done with regard to any sole traders within WA, or whether we had done anything, and then whether or not it was actually functional. Also, of course, any regulations or disallowance over that five-year period.

The CHAIR: Coming back to the Galbally report and recommendation 23, were there any concerns about adopting that particular recommendation here in Western Australia, either from the Department of Health or any of the stakeholders?

Mr Keen: I cannot speak for the entire Department of Health, but I can speak for my branch, which administers the current act on behalf of the department. There were not any, no.

The CHAIR: The other thing we are interested in is the commonwealth secretary. We were not too sure what it is and how it works within the Western Australian context?

Ms Daniels: There is also a question there about what the commonwealth minister does. I started going through the act, and short of providing you with the act all the way through, the briefest way I can respond to that question is: in reading through what the responsibilities of the secretary are, and to a certain extent equally the commonwealth minister, in that particular section, the responsibilities of the secretary are similar to the CEO within the other parts of this act. It would be granting exemptions, giving special conditions, publishing the results of certain findings —

Ms Carpenter: For any higher risk products, they would be responsible for making the determination that it was something that could be sold.

Ms Daniels: It is largely the role the CEO has within the rest of our bill.

The CHAIR: Now you might explain to us the role of the commonwealth minister, seeing as you have opened the door to that one.

Ms Daniels: In the documents that you have, I outlined the interaction on page 6 and 7, I think, of the document that I prepared. It is appendix 4. I have outlined the interaction from a commonwealth point of view with states and territories who are adopting what we are suggesting that we adopt. But the minister by legislative instrument may define certain therapeutic goods, set certain standards, enter agreements with the European Union and the British Pharmacological Society, and vary conditions on products and give exemptions. That is a brief overview of what the commonwealth minister can do.

The CHAIR: I note that there is a question about any proposed amendments to other acts being considered once this bill has passed and the answer you provided was no. I looked back at some of the acts and regs that relate to this bill. Will the Misuse of Drugs Act—which we know we have had three or four goes at trying to fix up areas of that legislation—the Health Practitioner Regulation

National Law and, one that I had not heard of at all, the Health Professionals (Special Events Exemption) Act, all stay as they are?

Ms Daniels: They are being amended as consequential in relation to the whole bill. But the answer to the question about part 6 is no because it is confined to natural persons producing therapeutic goods for supply within this state.

The CHAIR: We are not looking at the policy of this bill, that is not part of our role, unless we are directed to. So, really, our focus is trying to find a copy of that agreement and trying to determine what the role of the state will be. I think that you have answered that today in terms of having the capacity to disallow any regulations that the state is not comfortable with or satisfied with.

I am just trying to think if there is anything else that we need information on. We probably have about another month before we have to report. There may be a couple of other questions that come up during that period, once we get our heads around this legislation a little bit more, so we may come back to you just for a bit more clarification on some issues.

You were going to say something, Robyn?

Ms Daniels: I was going to make a confession, I suppose. That was when I looked at whether it was uniform legislation, was there an IGA, I have never seen an IGA as it is defined as an IGA. I actually had a discussion with Mark about it. It is, though, for this committee's worth, about adopting the legislation. But we will attempt to find—I understand it is important that we will track down what we can. That was what we were given in the time.

Hon MARK LEWIS: Just to follow up on that, that was in 2005?

Ms Daniels: Correct.

Hon MARK LEWIS: What interaction has WA had since that date?

Ms Daniels: With whom?

Hon MARK LEWIS: With the commonwealth; with the COAG mechanism.

The CHAIR: On this issue?

Hon MARK LEWIS: Yes, on this issue. We have just assumed that in 2005 this thing was signed off and we have had no more contact with COAG or through the COAG process or through any other mediation or relationship with —

Ms Daniels: This would be a personal comment. I think if you went through many COAG agreements and looked at every one of the recommendations and looked at whether they had been implemented, I think you would find there would be many. So, I would suggest that this is but one recommendation of COAG that has not been implemented here in Western Australia. My colleagues can speak for themselves, but I think that from a national point of view in trying to manage substances and ensure that the people of Western Australia or Australia are safe, that there would be constant reminders by other states that you have not fulfilled that. Again, that is my personal view. I will stop.

Mr Keen: I am uncertain whether or not this would have been passed to the health ministers under SCOH, as it is now, or previously under the Australian health ministers' council, simply to progress. Interactions at our level are really mostly with the Therapeutic Goods Administration, and I can say that it is definitely their expectation that this is done. We have been in contact with them formally in 2011 but also informally at regular intervals when we do meet. I think it is the commonwealth's impression or expectation that this is done nationally.

Ms Carpenter: Certainly, it has been brought up at the National Coordinating Committee on Therapeutic Goods, which did exist up until recently as subcommittee of AHMAC. At that group, it has been an agenda item regularly. Before NCCTG was disbanded, it had a representation from the chief pharmacist or equivalent of each of the departments, plus the commonwealth. As an agenda

item at those meetings, it was expected that it would be adopted by every jurisdiction. As Neil alluded to earlier, apart from Queensland, which is still formulating their new legislation, all the other jurisdictions apart from us at this stage have either adopted it or have it in law ready to be adopted.

[2.10 pm]

Hon BRIAN ELLIS: I am a bit confused: say we cannot find an agreement, what you are saying, Robyn, is that is not unusual? I am wondering if there is no formal agreement, is it just assumed that the states agree?

The CHAIR: There must be formal minutes somewhere. There must be a document.

Ms Daniels: All I can say is that was all that was provided to us when we sought it from Premier and Cabinet in the time frame. I would agree with the Chair that there would be formal minutes. My concern is, as again was expressed by the Chair, it being out of session there may not be minutes in relation to it.

The CHAIR: With this particular bill, are regulations being developed alongside it?

Ms Daniels: Yes.

The CHAIR: Any idea of the time frame when they will be ready to go?

Mr Keen: The consultation is in full swing and substantially complete. I would think probably about 12 months from now.

The CHAIR: Is there a time imperative for this bill to be passed? I know it has been hanging around since 2005, but is there a rush on it now to get it through Parliament?

Mr Keen: I am just trying to think—my personal answer would be yes! The current act, as I said, is fairly outdated; a bit sad and tired and difficult to work with—no more than that and no more than has already been debated in the Legislative Assembly. It is the expectation of most of our stakeholders that it will be passed relatively shortly. Other than that, no. Is there a dire need?

The CHAIR: There always is with every bill, I am sure.

I had one other question: thinking back to that discussion about black salve and thinking about how people are purchasing therapeutic goods, not necessarily manufactured here but manufactured overseas, buying them online: how is the TGA able to take action with online sales issues when there is a pool product like the one you described, or even in that black salve case, how effective are they in taking action against those types of sole traders to stop them from putting that type of product out there?

Mr Keen: I would say that anything that is actually imported legitimately comes through an Australian sponsor and the Australian sponsor then has to adhere to the laws. If you are importing something on an individual basis as a person, you are probably not bringing very much in. You are probably only using it for yourself. The risk, while it exists, is probably to you. Based on the very large number of products and the very porous borders that we have, that might be something that is not well managed, but I would have to talk to the TGA to get an exact answer. If you imported products of that nature and then started selling them onwards, that is a difficult situation. If you were an actual person and you were not selling them outside WA, I would expect you might not be captured.

Ms Daniels: Correct.

Mr Keen: If you were selling them onwards interstate and you were a fully-fledged importer, then you would be captured by the commonwealth law. The situation I think you are describing is when it is an individual person and it is just for their use.

The CHAIR: I was curious.

Mr Keen: It is possibly more about educating consumers as to potential dangers. For example, there would be nothing to stop you importing a PIP breast implant, if you could find any, taking that to your surgeon and saying, "Please put these in." However, if you were trying to sell those onwards, then that would be the sort of thing that we desperately want to stop.

Ms Carpenter: Certainly the TGA website has consumer information about the dangers of purchasing medicines online. But I think, as Neil said, they have more an advisory role in that space. The controls are essentially over those supplying to consumers rather than individual consumers directly.

The CHAIR: I was just curious. You see all sorts of weird and wonderful things advertised through the various types of social media that people use now. You wonder about the checks and balances of people accessing them and the problems afterwards.

Hon MARK LEWIS: There is also CITES—the Convention on International Trade in Endangered Species of Wild Fauna and Flora—which makes up a fair proportion of the medicinal herbal range as well; rhinoceros and all that sort of stuff, which are endangered.

The CHAIR: Thank you very much. That was very useful for us. If there are any further questions, we will come back to you. We look forward to your hopefully successful search for this mysterious document we would all like to read. Thank you very much for your time today.

Hearing concluded at 2.15 pm