COMMONWEALTH OF AUSTRALIA

Official Committee Hansard

JOINT STANDING COMMITTEE ON TREATIES

Reference: Treaties tabled on 30 March 2004

MONDAY, 10 MAY 2004

CANBERRA

BY AUTHORITY OF THE PARLIAMENT

INTERNET

The Proof and Official Hansard transcripts of Senate committee hearings, some House of Representatives committee hearings and some joint committee hearings are available on the Internet. Some House of Representatives committees and some joint committees make available only Official Hansard transcripts.

The Internet address is: **http://www.aph.gov.au/hansard**

To search the parliamentary database, go to:
http://parlinfoweb.aph.gov.au

JOINT COMMITTEE ON TREATIES

Monday, 10 May 2004

Members: Dr Southcott *(Chair)*, Mr Wilkie *(Deputy Chair)*, Senators Bartlett, Kirk, Marshall, Mason, Santoro, Stephens and Tchen and Mr Adams, Mr Bartlett, Mr Ciobo, Mr Martyn Evans, Mr Hunt, Mr King and Mr Bruce Scott

Senators and members in attendance: Senators Kirk, Marshall, Stephens and Tchen and Mr Adams, Mr Bartlett, Mr Martyn Evans, Dr Southcott and Mr Wilkie

Terms of reference for the inquiry:

Treaties tabled on 30 March 2004

WITNESSES

Committee met at 10.01 a.m.

Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products, done at Wellington on 10 December 2003

COBBOLD, Ms Christianna, Director, Trans Tasman Group, Therapeutic Goods Administration, Department of Health and Ageing

IBBOTSON, Mr Jeffrey, Legal Adviser, Trans Tasman Group, Trans Tasman and Business Management Branch, Therapeutic Goods Administration, Department of Health and Ageing

LACEY, Dr Gary Robert, Manager, Regulatory Policy, Trans Tasman Group, Trans Tasman and Business Management Branch, Therapeutic Goods Administration, Department of Health and Ageing

MATTHEWS, Ms Fiona Louise, Legal Adviser, Trans Tasman Group, Trans Tasman and Business Management Branch, Therapeutic Goods Administration, Department of Health and Ageing

SLATER, Mr Terry, National Manager, Therapeutic Goods Administration, Department of Health and Ageing

CHAIR—Good morning. I declare open this meeting of the Joint Standing Committee on Treaties. As part of the committee's ongoing review of Australia's international treaty obligations, the committee will review two treaties tabled in parliament on 30 March 2004. I understand that witnesses from the Department of Foreign Affairs and Trade and the Attorney General's Department will be with us for today's proceedings, with witnesses from other departments joining us for discussion of the specific treaties for which they are responsible.

I should remind witnesses that today's proceedings are being broadcast by the Department of Parliamentary Services. Should this present any problems for witnesses, it would be helpful if they would raise this issue now. To begin our hearing, we will take evidence on the Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products.

Although the committee does not require you to give evidence under oath, I should advise you that the hearings are legal proceedings of the parliament and warrant the same respect as proceedings of the House and the Senate. The giving of false or misleading evidence is a serious matter and may be regarded as a contempt of parliament. Do you wish to make some introductory remarks before we proceed to questions?

Mr Slater—Yes. The purpose of this agreement is to safeguard public health and safety by establishing a joint scheme between Australia and New Zealand for the regulation of therapeutic products. The joint scheme will harmonise the regulatory requirements of Australia and New Zealand for prescription, over-the-counter and complementary medicines; medical devices; and

other therapeutic products. The joint scheme is to be administered by a single regulatory agency to be established under Australian legislation.

The impetus for the agreement is the Trans-Tasman Mutual Recognition Arrangement. The agreement addresses Australia's obligation under the TTMRA to work with New Zealand to develop a more integrated trans-Tasman economy by removing regulatory impediments between the two countries, to enable goods to be traded freely between them. The agreement provides a framework for the joint regulatory scheme and also sets out the governance and accountability arrangements for the new regulatory agency.

Once established, the new agency will replace the Australian Therapeutic Goods Administration—the TGA—that is within the Department of Health and Ageing and the New Zealand Medicines and Medical Devices Safety Authority within the New Zealand Ministry of Health. The agreement will establish a new ministerial council comprising the Australian and New Zealand health ministers to oversee the agency and ensure its accountability for the operation of the scheme to the Australian and New Zealand governments. The agreement will also establish a five-member board for the agency, which will be responsible for the governance of the agency.

The new scheme will apply international best practice in the regulation of therapeutic products and will be based on the current regulatory scheme operated by the TGA. The agency will regulate the manufacture, supply, import, export and promotion of therapeutic products. Its activities will include: the setting of standards with which all products must comply; pre-market activities, including the evaluation of products; controls over manufacturing, including licensing of manufacturers and auditing; post-market activities, including monitoring, surveillance and recalls; and enforcement activities. The TGA currently operates on a full cost recovery basis. The new agency will also operate on a full cost recovery basis for all activities it undertakes in relation to the regulation of therapeutic products.

The national impact analysis outlines the benefits Australia can expect from the agreement. The key benefit for Australian consumers will be an enhanced and sustainable specialist regulatory capacity through the establishment of the single agency. Our therapeutic products industry will benefit from reduced regulatory compliance costs due to the replacement of separate regulatory controls in both countries with a single set of controls under which products can be supplied in Australia and New Zealand. This means that a therapeutic product sponsor will need to apply only once for a product licence to supply a product in both countries and then will need to comply with only one set of pre- and post-market regulatory requirements to continue to be able to supply that product in both markets.

Implementation of the agreement will require Australian and New Zealand legislation. To achieve a truly harmonised set of regulatory requirements, the ministerial council will also make rules and the managing director will make technical orders that will contain many of the regulatory requirements of the scheme. These instruments will be subject to parliamentary scrutiny by both the Australian and New Zealand parliaments. The process proposed for implementation of the agreement is set out in detail in the national impact analysis, at paragraph 24. Exposure drafts of the two bills and key rules are currently being developed cooperatively between Australian and New Zealand officials. It is proposed that they will be publicly released

to provide an important opportunity for stakeholder consultation before being introduced and tabled in parliament.

Once this legislation is passed, the agreement will be able to enter into force, allowing the ministerial council to commence operation and the rules and orders that will underpin the joint scheme to be made. The commencement of the joint scheme and the new agency will be linked to the commencement of the new legislation. The agency is planned to commence operations from 1 July 2005. The agreement was also tabled in the New Zealand parliament on 30 March this year and is currently being considered by the New Zealand select committee on health. I commend the agreement to this committee. It is a critical step in moving to implement a joint regulatory scheme that will significantly advance trans-Tasman regulatory cooperation.

CHAIR—Thank you very much. I was surprised to see in the regulation impact statement that there was no mention of the proposed Australia-United States free trade agreement.

Mr Slater—The United States free trade agreement is separate from this agreement. This agreement operates under the trans-Tasman mutual recognition requirements and is between Australia and New Zealand. As I understand it, New Zealand does not have a free trade agreement with the US.

CHAIR—There is a paragraph in the draft text of the Australia-US free trade agreement which contains a provision for promoting closer cooperation between the Therapeutic Goods Administration and the US Food and Drug Administration. It is just cooperation, but I would have thought that, given that the TGA is your whole area of purview, you would have mentioned it.

Mr Slater—The TGA already has an agreement with the US FDA, particularly in the area of pharmaceutical good manufacturing practice. In fact, we are the only country that the US recognises in the area of pharmaceutical good manufacturing practice. There is a tendency throughout the world at the moment to have cooperative agreements between regulatory agencies, but this agreement between Australia and New Zealand harmonises the standards and sets up a single agency to regulate both.

CHAIR—I understand: we are going to have a single agency, which will be an Australian and New Zealand agency, and that will be the one cooperating with the FDA in the United States.

Mr Slater—Exactly.

CHAIR—An argument has been made about having a dual country licence: Medicines Australia is concerned that having a medicine that is off patent in one country but still covered by a patent in another country may reopen demands in the other country. How do you respond to that?

Mr Ibbotson—We are conscious of the concerns of Medicines Australia. We are focusing our attention on the regulatory aspects of the quality, safety and efficacy of therapeutic products rather than on the patent aspects, but we think that some of the measures that we will have in place that will deal with the safety issues in particular will meet some of the needs and concerns of Medicines Australia. We are looking at it from the aspect of being able to trace products that

are on the market in both countries. I think that will have the same effect of ensuring that medicines that are patented in Australia are still protected by patent law in Australia.

CHAIR—Given that FOI legislation is different between Australian and New Zealand, how will FOI requests be handled with the new agency?

Mr Ibbotson—The freedom of information legislation in each country will be available. Each country has exemptions in place to protect business affairs including commercial-in-confidence information, and we are working through those arrangements at the moment to ensure that confidential information will be protected in both countries and there will not be a divergence of outcomes.

CHAIR—Will Australia be maintaining its separate clinical trials process?

Mr Slater—The clinical trials process for Australia is currently under review. That review incorporates New Zealand input. The desire is to produce a clinical trials regime for Australia and for New Zealand. That will be considered when the report comes to hand.

CHAIR—Will merits review decisions by the AAT and the Federal Court be retained?

Mr Slater—Yes, they will. There will be a special merits review process set up to enable merits review in each country. There will be a panel from which a principal panellist will chair the merits review process in either country. In Australia, that is anticipated to be conducted by the AAT, and the principal panellist who will chair that tribunal will be the President of the AAT. The process will enable each tribunal to refer a matter for review in the other country if justice will be best served.

Mr MARTYN EVANS—When the chairman asked about the impact of this in relation to the FTA, you indicated that you felt there was no significance in the fact that there was going to be consideration given to the United States free trade agreement. If one were to assume, for the sake of the argument, that the US FTA went ahead—and, obviously, that is on foot at the same time—there is quite a substantial degree of involvement in pharmaceuticals in that FTA and I think it is safe to assume that New Zealand will not have an FTA with the United States in the foreseeable immediate future. I find it hard to believe that that will not have some impact on this agreement.

What if, under that agreement with the United States, we were to then proceed, or to wish to proceed, to some greater degree of harmonisation—for example, with our TGA arrangements—so that there were less bureaucratic arrangements between us and the United States and, therefore, a much quicker approvals process but New Zealand was resistant to the process? We have close agreement with the US on this already but New Zealand has demonstrated a degree of reluctance in the past with the United States. Perhaps its relationship is less harmonious than ours. Are you saying that, if under this treaty we are locked in a very close relationship with New Zealand under TGA arrangements, that would be absolutely no impediment whatsoever to any greater degree of harmonisation under a FTA with the United States, which contemplates possibly greater harmonisation of TGA arrangements with the US?

Mr Slater—I think we should start from the point that the FTA is not harmonising arrangements between Australia and the US. It is an agreement—

Mr MARTYN EVANS—I am contemplating a scenario in the future.

Mr Slater—You did mention that it was an impediment for Australia harmonising with the US. I think we need to accept that we are harmonising with New Zealand. There will be an impact from the US free trade agreement, certainly on Australia's policy stance in regard to what it wants to achieve for access to medicines and other therapeutic goods. This agreement does not in any way harmonise Australia's policy and New Zealand's policy. It sets out to create a single regulatory agency that works to both governments and works to a ministerial council. Some of the policy challenges of difference of view which will emerge over time around maybe even access to therapeutic goods will need to be resolved by that ministerial council. Issues that may arise out of Australia's commitments under the free trade agreement with the US where there are policy differences will need to be considered by that ministerial council and consideration will have to be given as to how best to deal with them. For example, there is a difference already between the intellectual property protection that New Zealand has and Australia's scheme. Australia gives an effective patent life of around 15 years and I think that New Zealand's is somewhere around 11 or 12 years, so there are those issues to be managed in any event.

Mr MARTYN EVANS—But my question was entirely to the future.

Mr Slater—Yes, and I am saying that at the moment we have differences in policy stance, and in the future differences in policy stance will emerge and they will need to be resolved between the two countries as to how best the agency can operate and serve both governments. It needs to serve the policies of both governments.

Mr MARTYN EVANS—And we can do that with entirely disparate views on managing that future relationship with the United States. You are saying that we could move to harmonisation—and I am not suggesting that we are going to. I am saying that, under a relationship where we move theoretically to close relationships with the United States in the area of pharmaceutical regulation under an FTA with the US—which I am hypothesising we adopt for the purposes of this argument about this treaty—we could theoretically move to a close, integrated relationship with the US which assumed that New Zealand did not, for its own reasons internally—which one can easily contemplate ideologically. Is the treaty which we are looking at this morning sufficiently flexible, in your view, that we could live with a relationship where we move to close integration with the US but New Zealand refuses to?

Mr Slater—I think I would characterise it as not so much sufficiently flexible as that there are obligations that we would need to meet under this treaty which, in the event that we wanted to move our position away from that stance, we would need to discuss and resolve within the treaty framework with New Zealand.

Mr WILKIE—Is there anything in the treaty that would preclude that from happening?

Mr Slater—We are signing an agreement to set up a single set of standards, a single set of processes to approve products that come onto our market. There are provisions within this treaty to enable either country to opt out from this arrangement in the event that they feel the need in particular circumstances to do things differently. In the end, there are clauses to enable a divorce as well in the event that the agreement no longer suits the purposes of both countries. But this

treaty does give an obligation to both countries to implement a set of processes which produce an international first-class regulatory arrangement with common and harmonised standards.

Mr ADAMS—This is only going down the same track that we have been down with New Zealand in many other areas, isn't it?

Mr Slater—Yes.

Mr ADAMS—And my colleague is a bit concerned about it but I think it is a straightforward—

Mr WILKIE—No, it is just that this agreement was reached before the free trade agreement negotiations were taken into account.

Mr ADAMS—There is a ministerial council that can sort out issues, like we have done with food—

Mr MARTYN EVANS—The problem here is that we are signing up to two marriages.

Mr ADAMS—As long as it is legal.

Mr MARTYN EVANS—The Australian government, on behalf of the parliament, is becoming a little polygamous. If we were adopting that analogy, we are signing up to one relationship across the Pacific and another across the Tasman, in respect of pharmaceuticals. It is in dire need of a little marriage counselling because we are signing up to a discussion group with the Americans on pharmaceuticals and we are entering into an actual relationship in this context with the New Zealanders, as we have for a long time. We are entering into a relationship which will require us to have an ongoing, single consultative entity for approvals with New Zealand, which I suspect will be quite prescriptive about those approvals, whereas we are also looking at having the same kind of relationship with the United States under this FTA, which at the end of the day would take us down a path with them which is contemplated to be very similar in the long term.

Mr Slater—I have to challenge you about the similarity. The scheme in New Zealand is an agreement to set up a single market with a single regulatory agency that will make decisions with legal effect in both countries, chases down offenders in both countries and takes them to court in both countries. In other words, it is the regulator for Australia and, quite separately, it is the regulator for New Zealand. The US free trade agreement opens up cooperation in the area of trade by removing certain barriers; it does not lay down a harmonised system, it does not have a common set of standards for Australia and the US and it does not have a single agency to administer it in the two countries.

Mr MARTYN EVANS—I understand that now, but my whole question was predicated on where that agreement might lead us in the future. My concern also, given that the United States is the major promoter of the intellectual property in this arena, is about the preclusions in this treaty, given that New Zealand generates none of the intellectual property—that is, New Zealand is not the generator of this intellectual property. I can see no difficulty in the regulatory aspect of this, in terms of the actual advice to the process, but I am concerned about what it prevents us

from doing in relation to our relationship with the approval process of the FDA, for example, in the United States and what that may prevent in terms of harmonising that process and reducing the costs of these medicines to Australian consumers at the end of the day by having a third party in that relationship. We were actually seeking to reduce the approval costs and duplication between the FDA and the TGA, and that process would be complicated by having a third party in that negotiation. I am concerned as to what extent that will increase the cost of doing business in that context and I suspect that will also be a difficulty for us. Have we actually discussed this as part of our negotiations with the United States?

Mr Slater—Yes, it has certainly been included in discussions with the US that there are agreements. We have an existing agreement, as Mr Adams said, in the area of food, and other agreements with New Zealand existing set up under treaty arrangements. This will be a treaty arrangement. As I said, in the treaty there are provisions for differences of view and approach that take place and for special circumstances to be handled. In article 19 there is also a clause which enables the parties to agree on the association with any other third party. As I said, where there are desires that may affect the arrangements under other agreements, they can be discussed at the ministerial council.

Mr MARTYN EVANS—There would be a right of veto by New Zealand, though, wouldn't there?

Mr Slater—You used the word 'veto'. I would not use that word. I think there is a right of either party to expect that the other party will bring to the table any issues that impact on the treaty arrangements and on the scheme.

Mr BARTLETT—I am interested in the harmonisation process, where there are regulatory differences. Firstly, could you describe for us the extent to which those differences occur? Are they widespread or are they fairly minimal?

Mr Slater—In the area of prescription medicines and over-the-counter medicines, Australia and New Zealand have a very similar approach. New Zealand essentially do not regulate medical devices and have no regulatory scheme. In the area of complementary medicines, they do not regulate them as therapeutic goods. So the new scheme will need to introduce a regulatory framework for medical devices and complementary medicines. Australia has adopted the global harmonisation recommendations on medical devices. So the current state of play is that New Zealand has agreed that those recommendations would be the framework for regulating medical devices. As Australia is leading in the area of complementary medicines, the Australian regulatory framework for complementary medicines would certainly be the regulation starting point for negotiations around what will be the regulatory framework.

Mr BARTLETT—So we can be absolutely sure that there will be no reduction or lowering of regulatory standards in Australia to meet New Zealand's level.

Mr Slater—The primary objective of the treaty is to introduce first-class international regulatory framework that protects the public health and safety of Australians and New Zealanders. So an objective of the regulatory scheme is to see no diminution in standards in either country.

Mr BARTLETT—Are there any instances where we will need to raise our standards?

Mr Slater—Off the top of my head I cannot think of any.

Mr ADAMS—Are all those regulations driven by evidence?

Mr Slater—Yes, by scientific evidence.

Mr MARTYN EVANS—In the area of complementary medicines, how are you going to apply that? You made two contradictory statements there in relation to complementary medicines being driven by science.

Mr ADAMS—No, that is not true.

Mr MARTYN EVANS—New Zealand has a substantial green vote and the parliament has a significant element of that. How will you attempt to apply those standards in relation to science and evidence based medicine and so on? There will be calls for exemptions and grandfathering. How are we going to apply those standards in that context? I can see how it works in the traditional drug and medicine area. How does the treaty position us in relation to the whole complementary herbal Chinese medicine—

Mr ADAMS—Mutton bird oil.

Mr MARTYN EVANS—Green lipped mussel.

CHAIR—You have got the question now.

Mr MARTYN EVANS—You have the flavour.

Mr Slater—The expert committee examining the Australian regulation of complementary medicines has made 49 recommendations. The government is considering those and is involving New Zealand in the consideration of how best to apply those regulations, with the objective that both countries will agree on the amendments that might be made to the Australian framework to ensure that it is operating at best practice. It would then be the intent of both countries to adopt that best practice regulation for the new agency.

Mr MARTYN EVANS—How is that done then? By regulation?

Mr Slater—There is already an interim ministerial council which is looking at how to establish the agency and the regulatory framework. The two ministers have agreed that they will work together to look at reforms to the regulatory framework to ensure that they are suitable for adoption by the new scheme.

CHAIR—I want to ask you about direct-to-consumer advertising of prescription medicines, which is banned in Australia but is allowed in New Zealand and the United States. Is there anything in this treaty that will allow direct-to-consumer advertising in Australia?

Mr Slater—That is an issue of difference between Australia and New Zealand. The New Zealand government is currently examining that issue. There has been a press release from the New Zealand Minister for Health which says that it is the intention of the New Zealand government to harmonise with Australia in this area.

CHAIR—Did you want to say anything on the National Drugs and Poisons Scheduling Committee?

Mr Slater—The scheduling process will involve the new agency, as it involves the TGA at present. I should point out that drugs and poisons scheduling are given legislative effect through state and territory legislation and, in the case of the joint agency, through New Zealand legislation. New Zealand has its own legislative framework for regulating access to medicines by citizens. The new arrangements for the agency to adopt are being discussed at the moment with the states and territories and New Zealand. There is no intention to change the legislative means of effect for drugs and poisons scheduling. It will still be up to the Australian states and territories and the New Zealand government to implement the recommendations of the agency.

Mr MARTYN EVANS—I think you have done extremely well this morning in addressing the committee's questions, but one would have to conclude that you have not answered a single one of them. You have spoken an awful lot about intentions and goodwill and what governments would like to do, but you have not actually given us a single concluded answer today. I have every respect for the way in which you have answered the questions in relation to the government's brief. Every one of your replies has been couched in terms of intent. We do not actually know where any of these directions will take us. In relation to the chair's question on advertising, we know where you mean these things to take us. In relation to my questions, we know what intent the government has in relation to best practice and New Zealand. But we do not know what the regulatory framework will be, do we? We do not know what the answer on advertising will be. We do not know what form of regulation we will have. We do not know what measure of control the parliament will have. It seems to me that we do not have a concluded framework on any of these areas.

Mr Slater—What we have is a treaty which the two governments have signed. That treaty will lead to legislation being introduced in both countries. It will be up to the will of the parliaments in both countries as to whether that legislation is given effect, or whether it is amended, or how it is shaped in the end. I think it would be imprudent of me and disrespectful of the parliament to suggest anything other than the intent of the two governments.

CHAIR—Part 22 of the national interest analysis says that the Australian legislation will have things like parliamentary scrutiny and administrative and judicial review of agency decisions, functions, powers and so on. When will that bill be available?

Mr Slater—We are hoping the bill will be out for consultation in the next few months and introduced in the Spring sittings. It has to be introduced at a similar time in New Zealand.

Mr MARTYN EVANS—I understand what you are saying about the will of the parliament, but we do not even have a draft bill that expresses in physical form the will of the government let alone the will of the parliament. That is my concern. At this stage we have only the

theoretical will of the government. We do not even have the will of the government expressed physically in print.

Mr Slater—We start off with the treaty, and the treaty sets down what the two governments have agreed. That then leads to the ability to draft legislation which will be put before both parliaments.

Mr WILKIE—I think Mr Evans is saying that the treaty does not say what the governments want to achieve because it does not cover a lot of those areas that need to be addressed.

Mr MARTYN EVANS—It is even vaguer than—

Mr Slater—It sets out the intent of the—

Mr WILKIE—But an intent to discuss something is not—

Mr MARTYN EVANS—Isn't this saying that there is a direct—

Mr WILKIE—For example, with the US free trade agreement, certain legislation needs to come into force to make it happen, but the nuts and bolts are being discussed in the treaty so that we can look at what is being proposed. What we have here is something that says, 'We are going to get together and sort all these other things out,' but it is not specified in the agreement. On issues like the advertising of drugs, I think we really need to know what the position is going to be before we even consider going down the path of looking at the treaty.

CHAIR—Mr Slater, do you want to respond to that?

Mr Slater—The treaty is the first step in setting up the scheme. It sets out the key elements of the scheme, including the governance arrangements and the intent between the parties. That will be translated into legislation to be introduced in both countries. That legislation will have wide consultation before it is introduced into the parliaments of both countries and will be debated and considered by the parliaments of both countries. That is the process we are following.

CHAIR—Did you use FSANZ—which was previously ANZFA—as the model for the new regulator?

Mr Slater—In terms of forging the arrangements between the two countries using a treaty based model, yes, but FSANZ—Food Standards Australia New Zealand—only set standards. Those standards are given legal effect through Australian states and territories and the New Zealand parliament. The regulator does not have any legal powers in relation to legislating. This new agency will be given the power to approve products on the markets of both countries, to set standards for both countries, to enforce those standards, to issue recall notices and to have review processes and governance commitments which are quite different to FSANZ.

CHAIR—Are there any further questions?

Senator TCHEN—I think it should be a matter of record that Mr Evans's earlier observation about science and complementary medicine being a contradiction is a matter of personal opinion rather than a view of this committee or of other members of this committee.

CHAIR—As there are no further questions, on behalf of the committee I thank you for appearing to give evidence this morning.

[10.37 a.m.]

World Health Organisation Framework Convention on Tobacco Control, done at Geneva on 21 May 2003

KLAUCKE, Mr Klaus, Director, Tobacco, Drug Prevention and Youth Policy Section, Department of Health and Ageing

HEFFORD, Ms Jenny, Assistant Secretary, Drug Strategy Branch, Department of Health and Ageing

CHAIR—Welcome. Although the committee does not require you to give evidence under oath, I should advise you that the hearings are legal proceedings of the parliament and warrant the same respect as proceedings of the House and the Senate. The giving of false or misleading evidence is a serious matter and may be regarded as a contempt of parliament. Do you wish to make some introductory remarks before we proceed to questions?

Mr Klaucke—I have some brief remarks. On 21 May 2003, the 192 member states of the World Health Assembly unanimously adopted the text of the World Health Organisation's Framework Convention on Tobacco Control. The Department of Health and Ageing would like to note the importance of this action, since it is the first time that the WHO has exercised its powers to develop a global public health convention. The World Health Organisation estimates that, should current levels of tobacco use continue, 10 million people will die of related causes by the year 2030. This burden of death and disease translates into lost resources to the global economy. Ratification of the convention by Australia will consolidate our recognised leadership role in public health policies relating to tobacco.

Negotiations for the convention took almost four years, with Australia playing a prominent role in those negotiations. The text adopted in May last year is consistent with current domestic policy at a national and jurisdictional level. Australia will not incur any additional costs from the ratification of the convention. Any requests for assistance from developing countries on the issue will continue to be prioritised within the existing foreign aid structure, as they are now. No new legislation is required to give effect to the convention, since Australia and its jurisdictions already have comprehensive policies that, among other things, prohibit tobacco advertising, provide for health warnings on packaging and ban sales to minors. While the effects of the convention will be greater in other countries that have less stringent policies on this matter, Australia still has an interest in reducing the global harm caused by tobacco use, and ratification of the convention would play an important role in achieving this aim.

CHAIR—Thank you. Based on the NIA there are no obligations for Australia arising out of this treaty.

Mr Klaucke—Australia will be in compliance with the convention with their next existing policy and legislative frameworks—that is correct.

CHAIR—One area that people are now looking at is the retail space involved with tobacco. In California people are saying that tobacco companies are using displays and so on to make their product more attractive to minors. Is there anything in the treaty which addresses the use of retail space?

Mr Klaucke—There is nothing specifically on that issue, if you are referring to the placement of tobacco products—for example, in terms of their visibility. The convention does call on states to establish comprehensive bans or restrictions on tobacco advertising, promotion and sponsorship. I would think that would be an option that a state could choose to pursue, but there would be no mandatory obligation to address that particular issue.

Mr WILKIE—Is there anything in the convention that talks about tobacco sponsorship? I thought there was something that suggests that tobacco sponsorship through organisations which may give them an indirect benefit should not be encouraged.

Mr Klaucke—There is a definition in article 1, on the use of terms, which gives a definition for tobacco advertising and promotion. It speaks of:

...commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly ...

That does not cover sponsorship, but there is a further definition, which states:

...any form of contribution to any event, activity or individual with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly.

Mr WILKIE—Which one is that?

Mr Klaucke—Articles 1(c) and (g), relating to the use of terms.

Mr WILKIE—I suppose the question there is: how would that then relate to political parties receiving donations from tobacco companies in the form of support for election campaigns?

Mr Klaucke—My understanding from the negotiations in Geneva was that the intention was to capture sponsorship in the sense of labelling, for example, a sporting event the 'XYZ Tobacco Company Race' or whatever. Donations to organisations would not be considered advertising or sponsorship within the meaning of the convention.

Mr ADAMS—The 'Philip Morris Liberal Party' is accepted, is it?

CHAIR—Are you able to provide the committee with the latest statistics on smoking prevalence in Australia and on tobacco related deaths in Australia?

Mr Klaucke—Yes, we are. According to the National Drug Strategy household survey the current smoking prevalence rate in Australia among persons aged 14 and over is 19.5 per cent. The most recent estimate that we have of tobacco related deaths is 19,000 per year, which is an estimate by the Australian Institute of Health and Welfare.

CHAIR—As I understand it, amongst OECD countries Australia has the third lowest smoking prevalence after the United States and Sweden.

Mr Klaucke—I could not swear to the third lowest, but certainly it is one of the lowest.

Senator TCHEN—You told the chair that the current Australian regulations are in compliance with the convention's requirements, yet the NIA states that submissions were received from various tobacco companies. Some tobacco companies expressed concern that the convention goes beyond the current regulations. Can you expand on that?

Mr Klaucke—I believe that some of the tobacco companies' concerns relate to what they consider to be appropriate to include in an international convention on this matter. I believe they do have concerns about other countries adopting, for example, the kinds of restrictions on advertising that are provided for in the convention and that operate within Australia. I am not sure that those comments went solely to the reading of domestic law on this matter.

Senator TCHEN—On page 2 of the attachment to the national interest analysis, items 12 and 13 refer to the British Tobacco Company and the Imperial Tobacco Company, which consider that some of the proposed conventions go beyond what is reasonable. Stuart Alexander and Co. raised a similar concern: the conventions go beyond the existing regulations. Are you telling the committee that the existing regulations that are referred to are not Australian regulations but other countries' regulations?

Mr Klaucke—My understanding is that the comments made by the tobacco industry have related to the general drift of the convention—of what they saw as appropriate in relation to that. The legal position that we have is that we are in compliance with the convention within the existing legislation that we have.

CHAIR—Just on that point, are there any further regulations that need to be made under this convention?

Mr Klaucke—In order to give effect to the convention, no.

CHAIR—So there are no changes.

Senator TCHEN—I am fascinated by the reference to 'snus'. What is it?

Mr Klaucke—It is a form of oral tobacco. It is a kind of lozenge type product that one puts in one's mouth and sucks on.

Senator TCHEN—I see. Thank you very much. That sounds fascinating.

Mr WILKIE—It is amazing that we have a government signing up to a convention to do something which is very worth while but at the same time not refusing to take donations from the same people they are trying to rule against here for political purposes. It is a bit like governments making laws to prevent organised crime and taking donations from the mafia.

CHAIR—Do you want to phrase that as a question?

Mr WILKIE—No, it is just a—

CHAIR—It is an observation.

Mr ADAMS—It is a very good observation. I think it reflects on—

Mr BARTLETT—As to that observation—

CHAIR—That is enough observations.

Mr ADAMS—Mr Klaucke, did the WHO look at the future of tobacco and the difficulties of black market tobacco? Did it deal with issues such as winding it down, where it will come from and so on?

Mr Klaucke—They did. In fact some time back, under the auspices of the United States, there were some international discussions on the matter of illicit tobacco. I would need to take on notice any request for detail on that. Certainly there was discussion about strategies for dealing with black market or illicit tobacco, particularly the smuggling of it, and there are provisions in the convention that raise that issue.

Mr ADAMS—That is all right. As long as it is part of the process, I will catch up with that as it comes through. This convention deals with some of the display aspects and the way things are selling, I think. I rely on my Tasmanian experience for this. The state government down there has, over the last three or four years, banned most of the cigarette advertising in shops. It cannot be up front. Things have to be covered. It is quite an exercise in taking it away from major advertising, which I think the chair may have raised as a concern that he has.

Mr MARTYN EVANS—Has research been established internationally or in Australia which tracks the outcomes from advertising restrictions to reductions in smoking? Has a link been established between preventing people from looking at the product in an advertising sense and tracking outcomes—with people not taking up smoking or with smoking rates declining and so on—so that we can observe that this is having a positive effect?

Mr Klaucke—There have certainly been studies done both by individual researchers and, I believe, to some extent under the WHO itself showing that bans on advertising are one of the most powerful ways of preventing youth, for example, from taking up smoking. I would have to take on notice the detail of those studies, but such studies do exist.

Mr MARTYN EVANS—So that has been demonstrated to be one of the more effective techniques of preventing tobacco take-up?

Mr Klaucke—That is correct.

Mr WILKIE—Is the rate of young people taking up smoking increasing or decreasing in Australia?

Mr Klaucke—The statistics that we have tend to show that the rate among the 14- to 19-year-old group, for example, is not increasing rapidly. This is also something that is variable across

states. The most recent survey from the Institute of Health and Welfare, which was done in 2001, found that there had been an increase on the 1998 figure in the 20- to 29-year-old age group but not in the younger age group. There have been some recent state-level results since then. I would need to provide them on notice, if they were required.

Mr WILKIE—Have we done any studies into, say, Indigenous take-up rates in smoking? It is purely an assumption, but I would have thought that in many of those communities a lot of the young people would be taking it up.

Mr Klaucke—That is correct. Generally speaking, there is a higher rate of smoking and tobacco use among our Indigenous population than in the mainstream. Some estimates are that it is around 50 per cent of the population overall.

Mr WILKIE—Do we have any specific programs to target their participation? This is getting off the track a little.

Mr Klaucke—There are most certainly both state and federal programs in relation to Indigenous smoking. The federal government has recently provided $1 million for a centre of excellence in Indigenous tobacco control at the University of Melbourne. That would be to develop a kind of central register or a set of resources that could be used nationally to do some work with Indigenous health workers and in general to act as a kind of hub for the issue, to complement the various programs at state and territory level. There has also been developed under the auspices of the National Drug Strategy a complementary action plan which targets alcohol, tobacco and illicit drug use in the Indigenous population.

Mr WILKIE—Thank you.

Senator MARSHALL—When did the tobacco companies actually get on board this process?

Mr Klaucke—The tobacco companies have been consulted by the department at each stage of the negotiations. Whenever text has been provided by the World Health Organisation we have submitted that to them and to other stakeholder groups for analysis and comment.

Senator MARSHALL—Is there anything in the treaty that now requires them to actually tell the truth?

Mr Klaucke—I am not quite sure I understand the question, Senator.

Senator MARSHALL—They have a long history of lying about the effects of tobacco and the effects of their advertising on the take-up of tobacco use by young people. I was just wondering whether they have admitted that they do not have a record of telling the truth or whether the treaty now requires them to tell the truth in respect of these matters.

Ms Hefford—I think the question goes beyond the scope of the treaty. Certainly the treaty provides for controls in a number of areas that are replicated already in domestic policy—namely, controls around sale and advertising and things of that nature. If you want to go to the conduct of individual businesses, the treaty probably is an inappropriate tool to use. I am not quite sure how you would tackle the issue you are raising.

CHAIR—We have had a submission from the Cancer Council Australia. I think it has been posted on our web site. In that submission it says that they have extremely high prevalence rates in the South Pacific and South-East Asia amongst younger people and adults. Not all of them are signatories. What is the state of those countries' tobacco control measures? Is it rudimentary?

Mr Klaucke—It would be rudimentary in most of those cases. Indeed, one of the purposes of the convention was to encourage the uptake of the kinds of best practice policies that we have within Australia.

CHAIR—We can see that, in a country like Papua New Guinea, which is very close to us, 76 per cent of males and 80 per cent of females are smoking. But Papua is not a signatory to this convention.

Mr Klaucke—The question as to whether an individual country is or is not willing to sign or when it chooses to do so is ultimately a matter for that country's processes to decide. Beyond that it is difficult for me to comment.

Mr MARTYN EVANS—I would suggest that it might be useful to have a couple of paragraphs in our report on the actual effect of the advertising bans. If we could be provided with sufficient information to include that, it would be useful.

CHAIR—Do you have that information in your department?

Mr Klaucke—Yes.

Mr MARTYN EVANS—That would demonstrate the actual effectiveness of this, which goes to the core purpose of the treaty itself. I am not talking volumes of research—just a brief synopsis.

CHAIR—On behalf of the committee, I would like to thank you for appearing to give evidence this morning, Mr Klaucke.

Resolved (on motion by **Senator Marshall**, seconded by **Mr Adams**):

That this committee authorises publication, including publication on the parliamentary database, of the proof transcript of the evidence given before it at public hearing this day.

Committee adjourned at 10.58 a.m.