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JOINT COMMITTEE ON TREATIES

Reference: Treaties tabled on 11 May 1999

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JOINT COMMITTEE ON TREATIES

Monday, 7 June 1999

Members: Mr Andrew Thomson *(Chair)*, Senator Cooney *(Deputy Chair)*, Senators Bourne, Brownhill, Coonan, O'Chee, Reynolds and Schacht and Mr Adams, Mr Baird, Mr Bartlett, Mrs Crosio, Mrs Elson, Mr Laurie Ferguson, Mr Hardgrave and Mrs De-Anne Kelly.

Senators and members in attendance: Mr Adams, Mr Baird, Mr Bartlett, Mr Laurie Ferguson, Mr Hardgrave, Mrs De-Anne Kelly and Mr Andrew Thomson.

Terms of reference for the inquiry:

Treaties tabled on 11 May 1999.

WITNESSES

ATWOOD, Mr John, Acting Assistant Secretary, International Trade and Environment Law Branch, Office of International Law, Attorney-General's Department 31

HEWETT, Ms Kathryn Jane, Policy Adviser, Technical and Regulatory Barriers to Trade Section, Department of Industry, Science and Resources 31

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WILMINGTON, Mr Guy Daniel, Acting Manager, Technical and Regulatory Barriers to Trade Section, Department of Industry, Science and Resources 31

Committee met at 9.58 a.m.

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WILMINGTON, Mr Guy Daniel, Acting Manager, Technical and Regulatory Barriers to Trade Section, Department of Industry, Science and Resources

CHAIR—We are gathered to hold a public hearing into the proposed MRA with Iceland, Liechtenstein and Norway. On 11 May this year a number of proposed treaties were tabled in both houses of the parliament. As part of this committee's ongoing review of Australia's international treaty obligations, last week the committee looked at four of these proposed agreements. Today we are going to take evidence on the proposed MRA with Iceland, Liechtenstein and Norway and this will complete the committee's consideration of the proposed treaty actions that were tabled on 11 May. I welcome officials from the Department of Industry, Science and Resources, the Therapeutic Goods Administration, the Department of Foreign Affairs and Trade and the Attorney-General's Department, who are to give evidence on this proposed MRA. Although the committee does not require evidence to be taken under oath, these hearings are proceedings of the parliament and should be given the same degree of significance as are proceedings of the House and Senate, and false or misleading statements given may be regarded as a contempt of parliament. I say that for the record. Who would like to open the batting?

Mr Wilmington—I will, Mr Chairman.

CHAIR—Go ahead.

Mr Wilmington—Mutual recognition agreements on conformity assessment facilitate trade by enabling exporters to have their products tested and certified for compliance with the regulatory requirements of the importing country prior to export. They can deliver significant benefits for exporters by eliminating the time delays and costs associated with obtaining regulatory approval in the importing country. Mutual recognition agreements provide an alternative mechanism for meeting with the other country's requirements, but they are not the only means available. Australian firms can still choose to have their products assessed in the other country by one of their conformity assessment bodies.

The negotiation of mutual recognition agreements is a significant trade facilitation measure and as such is consistent with the government's overall trade objectives. By negotiating mutual recognition agreements, the government is delivering on its world trade obligations, in particular article 6.3 of the World Trade Organisation Agreement on Technical Barriers to Trade, which encourages members such as Australia to 'be willing to enter into negotiations for the conclusion of agreements for mutual recognition of results of each other's conformity assessment procedures'. Australia is leading the way in the development of bilateral mutual recognition agreements. The Australia-European Community Mutual Recognition Agreement was the first fully operational mutual recognition agreement of its type in the world and, depending on how one counts, this agreement would represent either the second or third.

While the Australia-European Community Mutual Recognition Agreement came into force on 1 January this year, it does not cover all countries that make up the European Economic Area. The European Free Trade Association members of Iceland, Norway and Liechtenstein are also members of the European Economic Area but are not part of the European Community. The participation of Iceland, Norway and Liechtenstein in the European Economic Area is governed by an agreement between the European Free Trade Association states and the European Community. On the one hand that agreement requires that the EFTA states will use the European regulations or directives as the basis of their own regulation; on the other hand the agreement states that where the European Community negotiates a mutual recognition agreement with a third country, such as Australia, it does so on the basis that the third country concerned will conclude an equivalent agreement with Iceland, Liechtenstein and Norway. Therefore, having negotiated a mutual recognition agreement with the European Community, Australia is morally obliged to negotiate a similar agreement with these three members of the European Free Trade Association.

The negotiation of a mutual recognition agreement with these three European Free Trade Association members also provides additional benefits at minimal cost by extending the number of countries for which a mutual recognition agreement applies. Since regulations for the European Free Trade Association members are identical to those that apply in the European Community, Australian conformity assessment bodies will not have to incur any additional costs or burdens in becoming designated under this new mutual recognition agreement.

There is one European country, Switzerland, that is not covered by either the Australia-European Community or the Australian EEA/EFTA mutual recognition agreements. Switzerland is part of the European Free Trade Association but is not a party to the European Free Trade Agreement. As a consequence, Australia is not morally bound to

negotiate a mutual recognition agreement with Switzerland. There has been one meeting between Australian and Swiss officials on the margins of one of the earlier rounds of negotiations for the Australia-European Community Mutual Recognition Agreement. Switzerland has yet to indicate formally any interest in negotiating a mutual recognition agreement with Australia.

The failure to enter into negotiations with Switzerland regarding a possible mutual recognition agreement does not, however, cause any practical problems to Australian exporters into Switzerland. It is our understanding that for all practical purposes Swiss regulatory officials will accept CE marked goods, regardless of their origin. Accordingly, having negotiated mutual recognition agreements with the European Community and the EEA/EFTA states, access to Switzerland is also achieved. However, Switzerland may wish to gain access to Australia's market on similar terms or may wish to formalise its understanding through the negotiation of a mutual recognition agreement. If we were so approached by Switzerland we would give this due consideration but would not preempt such a move.

I would like to turn to some specific issues, firstly in regard to participation in the mutual recognition agreement. While the mutual recognition agreement has been entered into by four countries, namely Australia, Norway, Iceland and Liechtenstein, the agreement in effect remains a bilateral agreement with Norway, Iceland and Liechtenstein acting as one party to the agreement. No single country can withdraw from the agreement without the agreement becoming inoperative. That said, the possibility of this occurring is very low and would be more detrimental to the EFTA members, given their ties with the European Community, than it would be to Australia.

With regard to the level of benefits, the department recognises that the level of direct benefits flowing to industries from this agreement alone is limited. Indeed, the level of trade between Australia and these three countries would not in itself justify the Australia-EFTA Mutual Recognition Agreement. However, it is linkages to the Australia-European Community Mutual Recognition Agreement which form the basis for the government's action in this area. On this point I note that the national interest analysis does not contain specific data for the level of trade between Australia and Liechtenstein. This is because neither the Australian Bureau of Statistics nor the United Nations will separately identify individual trade statistics for this country. This is due to the fact that Liechtenstein shares a common customs service with Switzerland and trade data for Liechtenstein is combined with that of Switzerland. That said, even if there is virtually no trade between Australia and Liechtenstein, there is potential for increased trade under the mutual recognition agreement.

On the issue of implementation, I would like to touch on a number of subtopics, the first being the agreement of the Australian states and territories. Given that some of the products covered by the mutual recognition agreement are regulated in Australia at the state and territory level, it was necessary to gain the support and approval of the states and territories to enter into this agreement. Their agreement has been obtained and is reflected in an intergovernmental agreement that was finalised on 30 November last year.

The next step is moving towards exchange of notes. Before proceeding to exchange of notes, the department will be ensuring that Australian legislation is positioned to do so. It was our understanding that this was the case and this is reflected in the national interest

analysis. However, it was drawn to our attention last Friday that a minor amendment is required to the national interest analysis in that an amendment is indeed required to the Therapeutic Goods Act with regard to the definition of conformity assessment bodies. A legislation bid has already been lodged in this regard and will be considered at the appropriate time. In light of this we will be reconfirming that all legislative changes that need to be done are carried out before exchange of notes takes place. This process of reconfirmation is not expected to delay the entry into force of the agreement. The requirement for the agreement to be tabled within 15 sitting days, in combination with the sitting roster, should provide ample time for this process to be completed.

With regard to entry into force, in accordance with article 14, the agreement will come into force on the first day of the second month following the exchange of notes. Again taking into account the sitting day roster, the earliest possible time for this to occur will be 1 November this year. To make the agreement fully operational, it will be necessary for Australia to designate conformity assessment bodies whose test reports, certificates and/or markings will be recognised by the regulatory agencies in the EFTA states. Given that the EFTA states adopt European Community directives and that a number of Australian conformity assessment bodies have already demonstrated their competence to test to these requirements by virtue of their designation under the Australia European Community Mutual Recognition Agreement, this process is expected to be only a rubberstamping activity on behalf of the EFTA states.

The committee has handed us correspondence regarding Nulite Systems and we are prepared to discuss these issues during the hearing. Thank you, Mr Chairman.

CHAIR—Would the TGA like to comment next?

Mrs Maclachlan—Mr Chairman, are there any specific comments that you would like me to address?

CHAIR—I suppose which particular industries or areas of manufacture within your purview are likely to be most advanced by it, and if there are any other witnesses who could add to that they could comment as well. It gives us a better idea if you explain such and such an industry, this kind of product, that is what is going to happen.

Mrs Maclachlan—The Therapeutic Goods Administration is a division of the Department of Health and Family Services. Through the Therapeutic Goods Act 1989, the Therapeutic Goods Administration has responsibility for the regulation of therapeutic goods manufactured in, imported into, or exported from Australia. Therapeutic goods encompass products such as medicines, pharmaceutical medicines, over the counter medicines, as well as complementary medicines and medical devices. This mutual recognition agreement covers good manufacturing practice, inspection of medicinal products, conformity assessment of medical devices—the whole process of assessing a medical device as being appropriate for the European market, whether it is the EC or the EFTA states.

Mr HARDGRAVE—Who can convince me that the agreement we have before us is not going to see a repeat of the EC's bureaucratic, rigorous requirements on Australian manufacturers? I do not want to concentrate on Nulite Systems International, but they did

provide an insight into how you lift the high jump bar a bit higher, and that automatically seems to freeze out Australian innovation. Can you convince me that this MRA with Iceland, Liechtenstein and Norway is not going to see a repeat of that?

Mrs Maclachlan—Under the mutual recognition agreement it is recognised that Australian manufacturers will have to meet the regulatory requirements, the technical requirements, of the European Community, and vice versa. The mutual recognition agreement does state that the parties will undertake and initiate harmonisation activities to whatever extent is possible. In relation to therapeutic goods, our standards for GMP inspection of medicinal products are equivalent to those in the European Community and in the EFTA states. Mr Tribe, our chief GMP auditor, will be able to address that.

In regard to medical devices, indeed the requirements are different. In some cases Australia's regulatory requirements are not currently as stringent as those of the European Community's, and in relation to the products that are being supplied by Nulite Systems—dental restorative materials—they are required to be listed on the Australian Register of Therapeutic Goods. They are currently classified as low risk listable products. The manufacturer must meet an acceptable standard of good manufacturing practice and that standard is the same standard as is required in the European Union. It reflects the European norm standard EN46000, either EN46001 or EN46002, depending on the level of manufacturing systems compliance the manufacturer requires. However, the difference between Australia and the European Community in regard to dental restorative materials is that here in Australia we require the manufacturer to declare that their product meets an International Standards Organisation standard, an ISO standard. That is a declaration that is supplied by the Australian manufacturer. We may follow up at any time and test the product to ensure that it does indeed meet that standard. In the European Union the requirements are slightly more rigorous in that the manufacturer has to have technical documentation which has to be reviewed as part of the manufacturing quality system review. Therefore, the Australian manufacturer has to meet a higher standard for his product to enter the European Community's market.

Mr HARDGRAVE—As a member of parliament representing Australians, I am very worried that we are not setting the world's highest standards on our medical equipment. Why is it that the Therapeutic Goods Administration has not insisted upon world's best practice for Australian standards rather than simply now waiting for an agreement to expose a failure? I suppose the other side of it is, not to throw all the blame on your shoulders, why the manufacturer is not realising that to be an effective market provider and, in fact, an innovator in the market requires setting a higher standard than the world currently has. Are the Europeans simply trying to lift that high jump bar higher to try and stop Australians from exporting innovations to their region?

Mrs Maclachlan—When we first entered into negotiations with the European Community on a mutual recognition agreement, we consulted with Australian industry to indeed raise the bar here in Australia. The Therapeutic Goods Administration is currently preparing a submission for the government's consideration to harmonise our regulatory requirements with those of the European Union. This will bring our standards into line with those internationally, and indeed we are not only working with the European Union but we

are working with the United States, Canada, and with Japan in the global harmonisation task force so that these major five jurisdictions have standards that are equivalent.

Mr HARDGRAVE—Who has the highest standards in the world?

Mrs Maclachlan—It would depend on what jurisdiction you spoke to. We believe that the European standards present international best practice. The global harmonisation task force is basing its requirements on the work of the European Union.

Mr HARDGRAVE—So what the TGA is supposed to do here is look at the goods manufactured, put a CE stamp on them—which means they are suitable for the European Community standard—and that should be good enough. If you say they meet the standard, theoretically this agreement should ensure that your assessment is accepted in Europe. That is the concept, is it not?

Mrs Maclachlan—That is true.

Mr HARDGRAVE—But what this agreement really has done is expose our standard as not being high enough.

Mrs Maclachlan—I think that the development of new legislation does take time. But we will be in a position, hopefully towards the end of this year, to actually introduce legislation to amend Australia's current regulatory requirements for medical devices.

Mr ADAMS—Are you saying it might be over-regulated?

Mrs Maclachlan—No, I certainly have not meant to give you that idea at all.

CHAIR—If in the case of these countries there is a very large multinational manufacturer, whether it is of pharmaceutical products or medical equipment, who has access by way of their patents to certain technology that others, especially smaller companies—for example, this one in Australia—do not, it seems a very simple method of erecting a non-tariff barrier to insist on a certain level of technology or standards, if you want to call it that, in a good with which that smaller company might want to compete. That seems to be what is behind this fellow, Nulite. He is competing against large multinationals with access to much greater R&D and so forth than him, and yet the high jump bar has been raised. You say you can find out what those standards are, you can help him reach them and certify it here; are you sure that is the end of the story—that once you issue that certificate, that is it? Is this agreement waterproof in that sense, that there is no backdoor way that they can say, 'Oh well, you may well have issued the CE certificate according to this agreement, this treaty, but you have forgotten this or this or this and we can keep them out.' Is this agreement adequate?

Mrs Maclachlan—Our responsibilities lie in certifying the product to the European requirements. If there are any other technical barriers to trade that may exist in individual member states, such as practices that hospital purchasing authorities may have, that really would be out of our control.

CHAIR—Can anyone else comment about that?

Mr Marengo—The answer to your question is a very strong yes. In fact, in a certain sense it goes beyond that. What the agreement does is to certify mutual confidence in each other's system of certification. The European Union trusts our system of certification in that we have signed the agreement, and that is the end of the matter.

CHAIR—But if other barriers are raised that is obviously outside the boundaries of this agreement?

Mr Marengo—Yes, of course, totally outside. So the answer to your question is yes.

Mr BARTLETT—Can I pursue the issue of potential costs and benefits. In your introductory comments, Mr Wilmington, you said that the benefits are limited. Has there been any attempt to quantify the extent to which Australian exports have suffered by having different standards to these three countries, or is there any evidence of their use as a de facto protective measure against Australian exports?

Mr Wilmington—There has been no direct assessment for these three countries. In fact, the amount of assessment done either by ourselves or other agencies on the benefits of mutual recognition agreements per se is very hard to quantify as it depends a lot on the actions and behaviours of particular companies. That said, there have been a number of economic studies, which suggest that, as a totality, technical barriers to trade posed by differences in national standards, technical requirements or conformity assessment regimes pose a significant barrier to trade. For example, in 1996 the OECD estimated that, depending on the product, differences in standards and technical regulations in different markets combined with the need for multiple testing of certification, may contribute between two and 10 per cent to the overall cost of production. In the automobile sector, the US and the European manufacturers estimated that the cost arising from different regulatory and certification requirements amounted to 10 per cent of design and environmental costs, and 65 per cent of manufacturers who responded to a 1995 OECD committee survey on consumer policy reported that testing and certification to satisfy mandatory requirements significantly increased the costs of manufacturing. So, given that this agreement addresses one element of those types of technical barriers to trade, there is potential for significant time and cost benefits to—

Mr BARTLETT—Yet you said earlier that the benefits are limited.

Mr Wilmington—The benefits are limited on the basis that the level of trade is not as big as it would be with some other key trading partners.

Mr BARTLETT—Has there been anecdotal evidence of this being used as a protective measure, artificially changing the standards or using it to unnecessarily delay import access et cetera?

Mr Wilmington—There has not been any evidence that we are aware of, apart from the fact that every country has its sovereign right to retest at the moment. That in itself has costs to Australian industry in having to have its product tested for each of the countries that it

wants to export to. The mutual recognition agreement in effect short-circuits that effect. In other words, you only have to have it tested once—and it can be tested here in Australia—and that will give you access to those multiple markets with only one testing, whereas in this case you would have to do three additional tests.

Mr BARTLETT—Would it be your view that signing this treaty would close that $61 million deficit that we have in trade with Norway, for instance, or increase it?

Mr Wilmington—It would have the potential to reduce the deficit because the costs for exporters to Norway, for example, would be replaced by reduced costs to enter that market. Therefore, entering that market should be easier and more exports should flow.

Mr BAIRD—I was wondering why Liechtenstein is included in this.

Mr Wilmington—Liechtenstein is included because it is a member of the European Economic Agreement through the EFTA states and the European Community. As I indicated in my opening statement, that agreement effectively morally binds Australia in the course of entering into an agreement with the European Community.

Mr BAIRD—So you are just closing the route in terms of these countries?

Mr Wilmington—That is correct.

Mrs DE-ANNE KELLY—I notice in the letter from the Minister for Industry, Science and Resources that he refers to the delays that Nulite Systems had. In his letter he says:

I have also been advised that the European Community's requirements for the category of medical device manufactured by Nulite Systems are more rigorous than the current Australian requirements. The European Community's requirements necessitated an on-site audit being undertaken which resulted in additional costs. This audit would not have been necessary to meet Australian regulatory requirements.

Is that additional cost and more rigorous assessment by the European Community going to continue?

Mrs Maclachlan—I think that until such time as we harmonise our regulatory requirements with those of the European Community there will be some duplication in cost.

Mr ADAMS—You mean catch up, improve our standards—not harmonise.

Mrs Maclachlan—In some cases our standards are equivalent to those of the European Community for high-risk devices, but the European Community system is different to ours at the moment. So there is duplication in audit requirements, yes. Under the Therapeutic Goods Act we are required to audit Australian manufacturers to Australian standards; under the MRA arrangement we are required to audit Australian manufacturers to the European requirements. What has occurred in this particular instance is, and I referred to it earlier, that technical documentation required to be reviewed at the on-site audit is not required under Australia's requirements but it is required under the European requirements.

Mrs DE-ANNE KELLY—I think our chairman put it very well with his questioning. Effectively then, Mr Hillis, there is a non-tariff barrier, isn't there?

Mr Hillis—It probably is fundamental at this stage just to mention the central principles of the WTO—the World Trade Organisation—Agreement on Technical Barriers to Trade. The basic principle behind this agreement is that standards, technical regulations or conformity assessment procedures do not become unnecessary obstacles to trade. In any situation where a standard or technical regulation is put in place, the implementing country has to identify what is known as a legitimate objective, and in many cases it is things such as human health and safety. These are not defined in the agreement but that is one of the ones that could be included. In most cases, if the technical regulation flows directly from an international standard there is an assumption that it is in conformity with the agreement.

In some cases, however, individual countries may decide that for particular geographic, climatic or personal reasons they may wish to go beyond an international standard. The situation here may well be one where you have some countries following an existing international standard and some countries going beyond it. This leads to one of two situations: firstly, either you have a problem in trying to meet one another's technical regulations—the situation can be referred back, for example, to the International Standards Organisation to review the existing standards—or, secondly, as in the case here, we enter into a mutual recognition agreement whereby, without altering one another's standards or technical regulations, we agree that we will do our product testing in conformity with their standards in order to be able to facilitate trade.

Mrs DE-ANNE KELLY—But I think the chairman's point was well made. In the letter from NSI dated 20 May he makes the point that both of the departments here in Australia—and I assume that is the Therapeutic Goods Administration and the Department of Industry, Science and Resources—were unprepared for the requirements of conformity assessment with the European Community. That meant that NSI was precluded from trading in the EC until it was accredited. However, there were no restrictions on the importation of EC goods. So the chairman's point is absolutely right: a small, innovative Australian manufacturer was disadvantaged because there is not harmonisation of approach in assessment. It seems to me that he is saying that the departments were unprepared, which is probably a kindly way of putting it. Can I have your comments on that, Mr Hillis?

Mr Hillis—I am afraid I would not be in a position to comment directly upon that because, as I said, we deal predominantly with the broader aspects of trade policy. We have not had much dealing with the specific instance that you are talking about here. But I would like to reiterate, nonetheless, that if Australia follows an international standard that does not mean that Australia's standards are in any way less effective than would be required. It seems that we are facing a situation where we have an international standard, plus the situation here. It may well be that the catch-up that we are talking about is whether or not there is going to be a general move by all countries to adopt that type of practice.

Mr BAIRD—So it seems in short that what we are talking about here is something worth while that we should be doing. One feels that we are not going to have something that is going to break our trade barrier with Iceland and Liechtenstein, but it is still something that we should be doing.

CHAIR—Is using one of these jurisdictions, Iceland, Liechtenstein or Norway to get certification and so forth, a reliable way into the whole European Union market? Is it possible with this agreement to appoint an agent—more or less because they are in the EFTA group but not in the EU—in Iceland for some piece of equipment, certify it, get it traded, and then use them to market your device through the EU?

Mrs Maclachlan—Yes, it is. This agreement will bring in all the member states of the European Economic Area.

CHAIR—But can all those Brussels authorities, in effect, impose a standard on Iceland, even though Iceland is in the free trade group but not in the EU?

Mrs Maclachlan—Certainly in the pharmaceutical and medical device sectors, yes.

Mr Wilmington—In essence they can, by virtue of the agreement between these three EFTA states and the European Community. As I said, one of the sides to that agreement is that these three EFTA states will adopt European Community directives.

CHAIR—Like New Zealand and Australia—a similar sort of thing in reverse?

Mr Wilmington—I think we have more separation. We do not have any agreement which says that New Zealand will adopt our standards.

CHAIR—Yes, fair enough. That is an interesting one. If a European manufacturer can get something into New Zealand under their technical standards, then for that matter it is in the Australian market too, isn't it?

Mr Wilmington—No, they still have to meet the requirements of either Australia or New Zealand.

CHAIR—They do, right.

Mr Wilmington—One of the basic tenets of these types of mutual recognition agreements is that we test to the importing country's requirements, whatever they are, and vice versa—they test to ours. We have no loss in any protection we can offer to Australian citizens under our laws because they have to test to our requirements before we get imports into Australia.

Mr HARDGRAVE—Are there literally five standards of a product floating around the world then? If the Europeans set the world's highest standards plus and the Americans then, say, have the world standard and we have the world standard or whatever, does that mean there are now five different grades of product quality or safety or whatever floating around the world?

Mr Wilmington—Potentially, yes. As I indicated before, that is the type of problem we are trying to address through this mutual recognition agreement. It is these differences in standards and technical requirements that in those three studies that I referred to pose up to a 10 per cent additional cost on the making and exporting of a product. It is those types of

things that, with this mutual recognition agreement and other initiatives in line with the WTO TBT agreement, the government is trying to reduce the effect of.

CHAIR—We will understand this much better than we did in the beginning.

Mr ADAMS—Nobody can give us an understanding of what is in it for our manufacturing industry. Does anybody want to give us an indication?

Mr Wilmington—Basically by reducing the number of tests that need to be done. Under current arrangements, you would probably have to do three separate tests for these three states. Under the mutual recognition agreement, an Australian manufacturer can get away with one test for those three countries. You can also have the test done here in Australia, which means the person who is going to be doing the testing will be closer, the manufacturer does not have to wait for the time delay if you are dealing with complications. The testing body is more accessible. We see the potential for a reduction in fees, even by the European bodies, for conformity assessment activities because they were will be in direct competition now with Australian conformity assessment bodies under this agreement. We also see reductions in the shipping costs involved because of now having to send a sample to be tested across to Europe and bring it back, and that can occur multiple times if the test fails the first time around. That in itself also has some reductions in time delays because you do not have to wait to ship the sample and ship it back; large samples which you have to send by sea can result in significant time delays. They are the types of advantages that we see that this mutual recognition agreement offers.

Mr ADAMS—At the moment because the Europeans have a higher standard than we do, they have an advantage, do they not?

Mr Wilmington—Regardless of the level of standard, this mutual recognition agreement does not try to address the differences in standards. This agreement only provides an alternative and potentially cheaper way to meet those standards.

Mr ADAMS—Until we get harmonisation under the world trade situation?

Mr Wilmington—That is correct.

Mr ADAMS—The NIA states that goods that go into New Zealand are treated as if they come from Australia.

Mr Wilmington—It is a common point of origin, as far as consideration of whether the goods fall under this agreement or not; Australia and New Zealand are treated as a common exit point.

Mr ADAMS—And that is because of our closer economic relationship with New Zealand?

Mr Wilmington—Yes.

Mr Hillis—I might add just one other potential benefit for Australia. The Office of Regulation Review points out in its regulatory impact statement that, in view of the additional costs that would be incurred in having a product tested in the countries mentioned in the MRA, it is not unlikely that those countries would wish to continue having their products tested in Australia, thereby benefiting Australian testing agencies and organisations, in preference to having them tested on-site.

Mr ADAMS—Are our manufacturers up to ISO standards? Is that what we use?

Mrs Maclachlan—In relation to medical devices, yes, we accept international standards.

Mr ADAMS—What other issues are we dealing with then with this agreement?

Mr Wilmington—This agreement is mainly directed to the cost of showing that the product meets whatever standard is specified.

Mr ADAMS—But what products are we talking about?

Mr Wilmington—In the case of TGA we are talking about medical devices and pharmaceuticals, and then there are automotive products; electrical equipment, basically low voltage equipment, which is domestic appliances; telecommunications terminal equipment—telephones, fax machines and so forth; the electromagnetic compatibility components of that electrical equipment; machinery; pressure vessels. There are eight product sectors in all and that covers it.

Mrs DE-ANNE KELLY—Mr Hillis has already confirmed that this is an international standard plus in terms of what the European Community applies to medical devices exported from Australia. So obviously, as the chairman has said, there is a higher barrier for our manufacturers to jump, whereas importers into Australia are taking advantage of a much lesser standard here. When is this harmonisation going to take place, Mrs Maclachlan?

Mrs Maclachlan—We are preparing a submission for the government's consideration at the moment—for the Minister for Health and Aged Care. We have undertaken extensive consultation with all stakeholders—industry, professional organisations and consumers. We are addressing the issues that have been raised by the Industry Commission in its report into the medical equipment and scientific equipment industries, and we are just completing an economic analysis that is required to support a regulation impact statement to support the submission to the government. So we are looking to the next parliamentary spring session. One comment I have about Australia's lower standards is that they are not necessarily lower as we do not require the documentation to be provided with an application. All medical devices that are supplied in Australia that come within the scope of the Therapeutic Goods Act cannot be supplied in Australia until they are included in the Australian Register of Therapeutic Goods. The Australian Register of Therapeutic Goods requires that products meet labelling, advertising, and, in some cases, product performance standards as well as standards in relation to the manufacture of the products. So Australia does have a very good standard, but there are in some instances extra requirements at the moment that have to be met by manufacturers who want to export to the European Community. But Australia does

have, and is recognised internationally as having, a very sound standard of regulation for medical devices.

Mr ADAMS—What is the percentage of imports versus exports at the moment?

Mrs Maclachlan—In relation to medical devices?

Mr ADAMS—Yes.

Mrs Maclachlan—The great majority of medical devices that are supplied in Australia are imported. We understand that about 85 per cent of products are imported into Australia. However, Australia's manufacturing industry is a very strong exporter, is very successful and is considered to have a very high standard worldwide.

Mr ADAMS—But it only gets 15 per cent of a local market?

Mrs Maclachlan—Yes.

CHAIR—Concluding this hearing completes the collection of the evidence regarding the group of treaties that were tabled on 11 May. On behalf of my colleagues I would like to thank all the witnesses who have appeared at the hearings. We intend to table a report on these treaties before parliament rises at the end of June.

Resolved (on motion by **Mr Adams**):

That the committee authorises publication of the evidence given before it at public hearing this day.

Committee adjourned at 10.43 a.m.