The Parliament of the Commonwealth of Australia **REPORT 22 FIVE TREATIES TABLED ON 11 MAY 1999 Joint Standing Committee on Treaties** June 1999

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Conclusions and Recommendations

Proposed Investment Promotion Agreement with India

The Committee supports the proposed *Agreement on the Promotion and Protection of Investments with India*, and recommends that binding treaty action be taken (paragraph 2.42).

Proposed Investment Promotion Agreement with Lithuania

The Committee supports the proposed *Agreement on the Promotion and Protection of Investments with Lithuania*, and recommends that binding treaty action be taken (paragraph 2.68).

Proposed Trade and Economic Relations Agreement with Fiji

The Committee supports the proposed *Trade and Economic Relations Agreement with Fiji*, and recommends that binding treaty action be taken (paragraph 2.88).

Proposed amendments to the Constitution of the World Health Organization

The Committee supports the proposed Amendments to Articles 24 and 25 of the Constitution of the World Health Organization, and recommends that binding treaty action be taken (paragraph 3.18).

Proposed Mutual Recognition Agreement with Iceland, Liechtenstein and Norway

The Committee supports the proposed *Mutual Recognition Agreement with Iceland, Liechtenstein and Norway*, and recommends that binding treaty action be taken (paragraph 4.82).

1

Introduction

Purpose of the report

- 1.1 This Report contains advice to the Parliament on the review by the Joint Standing Committee on Treaties (the Committee) of the following, proposed treaty actions which were tabled on 11 May 1999:
 - the proposed Agreement on the Promotion and Protection of Investments between the Government of Australia and the Government of the Republic of India, in Chapter 2;
 - the proposed Agreement on the Promotion and Protection of Investments between the Government of Australia and the Government of the Republic of Lithuania, in Chapter 2;
 - the proposed Agreement on Trade and Economic Relations between the Government of Australia and the Government of Fiji, in Chapter 2;
 - proposed Amendments to Articles 24 and 25 of the Constitution of the World Health Organization, in Chapter 3; and
 - the proposed Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the Republic of Iceland, the Principality of Liechtenstein and the Kingdom of Norway, in Chapter 4.

Availability of documents

1.2 The advice in this Report refers to, and should be read in conjunction with, the National Interest Analysis (NIA) prepared for each proposed treaty action. These analyses are prepared by the government agency responsible

- for the administration of each treaty, and are tabled in Parliament as aids to parliamentarians when considering the proposed treaty actions.
- 1.3 Copies of each of the treaties considered in this Report, and the NIA prepared for each treaty, can be obtained from the Treaties Database maintained on the Internet by the Department of Foreign Affairs and Trade (www.austlii.edu.au/au/other/dfat/), or from the Committee Secretariat.

Conduct of the Committee's reviews

- 1.4 Our reviews of each of the treaties considered in this Report were advertised in the national press, and on our web site at: www.aph.gov.au/bouse/committee/jsct/. A number of submissions were received in response to the invitations to comment contained in the advertisement. A list of these submissions is at Appendix B.
- 1.5 For these proposed treaty actions, we gathered evidence at public hearings on 31 May and 7 June 1999. Appendix C lists witnesses who gave evidence at those hearings.
- 1.6 Transcripts of the evidence taken at those hearings can be obtained from a database maintained on the Internet by the Department of the Parliamentary Reporting Staff at: www.aph.gov.au/hansard/joint/ committee/comjoint htm, or from the Committee Secretariat.
- 1.7 Additional material received during our review is listed at Appendix D.
- 1.8 In the normal course of events, we aim to consider and report on each proposed treaty action within 15 sitting days of it being tabled in Parliament. In the case of the treaty actions tabled on 11 May 1999, the 15 sitting day period would have expired on 23 August 1999.²

¹ The review of these proposed treaty actions was advertised in *The Weekend Australian* on 15/16 May 1999, p.2.

² The 15 sitting day period is derived from counting the number of days from 11 May 1999 when the Senate and the House of Representatives were both sitting on the same day.

Three trade and investment treaties

Background

- 2.1 Trade and investment agreements have been considered in a number of previous reports of this Committee:
 - First Report: Trade and Economic Cooperation Agreement with Romania;¹
 - 4th Report: Promotion and Protection of Investments Agreement with Peru, and Reciprocal Promotion and Protection of Investments Agreement with Chile;
 - 7th Report: Trade and Investment Agreement with Mexico;
 - 8th Report: Trade and Economic Cooperation Agreement with the Czech Republic;
 - 10th Report: Economic, Trade and Technical Cooperation Agreement with the Lebanon;
 - 11th Report: Economic and Commercial Cooperation Agreement with Kazakhstan, and Trade and Economic Cooperation Agreement with Malaysia;
 - 15th Report: Investment Protection and Promotion Agreement with Pakistan; and

¹ This Agreement with Romania was not the subject of specific comment in that report.

- Report 20: Trade and Economic Cooperation Agreement with the Ukraine.
- 2.2 The Department of Foreign Affairs and Trade (DFAT) noted that there are generally three planks in the raft of legal agreements signed with economies in transition:
 - double taxation agreements (DTAs);
 - Investment Promotion and Protection Agreement (IPPAs); and
 - trade agreements.2
- 2.3 DTAs seek to increase trade and investment between the parties by seeking to prevent the double taxation of income where this is received by a resident of one of the parties from activities in the other country. This is achieved by separating the parties' taxing powers and, in certain circumstances, by giving credits for the payment of tax in the other country.³
- 2.4 IPPAs might give wider most favoured nation (MFN) treatment for investments, and require that an investment by an Australian company be treated as would any other company. Such agreements also include dispute resolution procedures and use of the *Convention on the Settlement of International Disputes between States and Nationals of Other States* (ICSID). They are clearly of benefit to the commercial interests of both parties, and having them in place can facilitate investment.⁴
- 2.5 Trade agreements are the weakest of the three planks: essentially they are trade treaties with some wider commercial encouragement. Much of what they deal with is the commercial relationship between bodies that are not themselves parties to treaties that are made between governments. Although they include the principle of MFN status, the enforcement provisions are weak and investment disputes as such are not addressed.⁵

² Greg Rose (DFAT), Transcript of Evidence, 30 September 1997, p. TR15

³ DFAT, Submission No 3 (Proposed IPPA with Lithuania), p. 2. See also Joint Standing Committee on Treaties.(JSCT), Australia's Withdrawal from UNIDO & Treaties Tabled on 11 February 1997, 7th Report, March 1997, p. 15

⁴ Michael Lennard (Attorney-General's Department), *Transcript of Evidence*, 30 September 1997, p. TR10; Greg Rose (DFAT), *Transcript of Evidence*, 30 September 1997, p.TR15. DFAT, *Submission No 3* (Proposed IPPA with Lithuania), p. 3

⁵ Michael Lennard (AGs), Transcript of Evidence, 30 September 1997, p. TR10; Greg Rose (DFAT), Transcript of Evidence, 30 September 1997, p. TR15

Trade and investment agreements

- 2.6 With general application to trade and investment agreements, the Australian Government recognises the importance of promoting the flow of capital for economic activity, and its role in expanding economic relations and technical cooperation, between countries. It considers that investment relations should be promoted and economic cooperation strengthened in accordance with internationally accepted principles of mutual respect for sovereignty, equality, mutual benefit, non-discrimination and mutual confidence.
- 2.7 The Government acknowledges that investments and associated activities, of investors of one Party in the territory of the other Party should be conducted within the framework of the laws, regulations and investment policies of that other Party.
- 2.8 Such Agreements are intended to facilitate the pursuit of these objectives by providing a clear statement of principles about the protection of investments, combined with rules designed to make the application of the principles in trade and investment agreements more effective within the territories of both Parties.
- 2.9 In particular, negotiations for IPPAs are based on the Australian Model investment Promotion and Protection Agreement (the Model text).6

Proposed Investment Promotion Agreement with India

Reasons for the proposed treaty action

- 2.10 By guaranteeing certain treatment for investors, the proposed IPPA is intended to encourage and facilitate bilateral investment by citizens, permanent residents and companies of Australia and India. The proposed Agreement will be entered into in accordance with the Australian Government's objectives, set out above.
- 2.11 Australia and India already have a DTA, so this proposed IPPA forms an important cornerstone in the economic relationship between the two

⁶ This section contains general information drawn from the National Interest Analyses (NIAs) for the trade and investment agreements considered below.

- countries. It will provide certainty for Australian companies seeking to invest in India, in terms of an Indian commitment not to discriminate against them. It will also set out a clear means for resolving disputes, should they arise.
- 2.12 Ratification and implementation of the proposed Agreement will provide a stable, certain and consistent base for both countries to move forward in the conduct of our international business relations.
- 2.13 The Indian economy has made considerable advances in recent years and is now far more liberalised than at any other time in its history. Successive Indian governments have worked to reduce tariff barriers and to open the economy to foreign investment. While much remains to be done to transform the Indian economy into a truly open and internationalised market for trade and investment, its governments have stayed the course in pursuit of economic reform.
- 2.14 There are, however, protectionist forces in India, so that the proposed IPPA will provide a level of certainty and protection for Australian business interests. There is also a degree of political uncertainty in India, and an agreement signed by both Governments will provide greater guarantees for Australian businesses wanting to trade and invest there.⁷

Australia-India trade and investment

- 2.15 In 1998, Australia's merchandise exports to India were worth \$A2.15 billion, making India our 11th largest export market. While trade largely comprises traditional commodity exports, including coal, wheat, and wool, India has increasingly become the focus of efforts to export automotive components and services. There is also interest in exporting education and health services.
- 2.16 There has also been increasing interest among Australian companies investing in India over recent years, and this was one of the reasons why Australia entered into negotiations for the proposed IPPA. Australian companies are substantially involved in India. Australia is the ninth-largest investor, with foreign direct investment of more than \$A700 million, with over 100 Australian companies represented in India. That investment currently covers banking and financial services, manufacturing, hotels, minerals-processing, food-processing and the oil, gas and automotive sectors.

⁷ Unless otherwise specified, material in this section has been drawn from the NIA for the IPPA with India, p. 1, and from *Transcript of Evidence*, Glenda Gauci (DFAT), 31 May 1999, pp. TR17-18, 24.

- 2.17 The status of these investments vary considerably, both in terms of their state of development and profitability. Some Australian companies are investing to position themselves for opportunities that will arise as a result of further liberalisation of the Indian market.
- 2.18 Many Australian companies have elected to invest in the Indian market in joint ventures with Indian partners. This is because of the complexity of local rules, and a recognition of the importance of local expertise. The creation of such joint venture companies, with substantial Australian equity, is a further source of profit for Australian companies in the Indian market.
- 2.19 A further promising trend in Australian investment has been the trade benefits accruing from Australian companies investing in processing and infrastructure projects, and importing materials from Australia. DFAT believes that there is potential for further growth in such investment, and for concomitant growth in Australian exports.
- 2.20 Major opportunities for Australian investment are therefore likely to emerge from the massive development needs of India's mining and minerals processing, energy, information technology, telecommunications and infrastructure sectors.
- 2.21 India also has significant investment in this Australia. For example, the Mount Lyell copper mine in Tasmania was purchased by Indian interests for about \$A240 million. Another recent Indian investment was \$A500 million in a urea fertiliser plant in Western Australia.⁸

Obligations imposed by the proposed treaty action

- 2.22 The Agreement proposed provides a clear set of obligations and commitments relating to the promotion and protection of investments. Although Australia's Model text for IPPAs provided the basis for the negotiation of this proposed Agreement, there were some departures from it. These were included because India has its own model for IPPAs, and it was necessary to marry it with Australia's Model text. The resulting document protects Australia's national interest, honours the intent behind the provisions of the Model text and conforms to Australian standards of investment protection.
- 2.23 The principal areas of the departures from the Australian model were:

⁸ Unless otherwise specified, material in this section was drawn from Glenda Gauci (DFAT), *Transcript of Evidence*, 31 May 1999, pp. TR24-25, 23, and DFAT, *Submission No 2*, p. 1.

- Coverage of indirect investment in Article 1(h) that sought to define more specifically 'control' of a company to provide clear guidance on the proposed IPPA's application to companies incorporated in third countries.
- The limited guarantee of non-discrimination between domestic and foreign investors to accord National Treatment to investors.
- The provision of National Treatment and MFN treatment for forms of settlement in Article 8. The Australian Model only provides MFN.
- A provision (Article 12.3) that a dispute between the Parties will only be referred to ICSID if India agrees. India is not a party to this international convention.
- 2.24 Notwithstanding these changes from the Model text, this proposed Agreement conforms to Australian standards of investment protection.
- 2.25 Compliance with the proposed IPPA has few foreseeable direct financial costs for Australia.9

Date of binding treaty action

2.26 The proposed Agreement shall enter into force 30 days after the date on which the Parties have informed each other that their Constitutional requirements for bringing it into force have been completed. It is proposed that Australia's notification to this effect be passed to the Government of India after 9 August 1999.¹⁰

Consultation

- 2.27 No negative comments were received from that States and Territories, following presentation of the text to the Standing Committee on Treaties (SCOT).
- 2.28 The Australia-India Business Council (A-IBC) monitored the negotiations and welcomed the proposed IPPA. It has been seeking such an Agreement with Australia 'for some years'. The Council was supportive because the proposed IPPA would encourage an environment conducive to the flow of

⁹ Unless otherwise specified, material in this section was drawn from the NIA for the IPPA with India, pp. 1-2, from *Transcript of Evidence*, 31 May 1999: Glenda Gauci (DFAT), pp. TR 18, 19, 21, and Richard Rowe (DFAT), pp. 21-22.

¹⁰ NIA for the IPPA with India, p.1

investment between the two countries, thus strengthening the bilateral relationship.¹¹

Withdrawal

2.29 After an initial period of ten years, the proposed Agreement shall remain in force indefinitely unless one of the Parties gives one year's written notice of termination. For existing investments, it shall continue to be effective for a further period of 15 years from the date of termination.¹²

Evidence presented

- 2.30 In addition to the matters discussed elsewhere in this consideration of the proposed IPPA, at the public hearing we also took evidence on:
 - the provisions of ICSID; and¹³
 - negotiation of a draft Memorandum of Understanding (MOU) on tourism with India.¹⁴

Testing of nuclear weapons, clashes in Kashmir

- 2.31 The testing of nuclear weapons in South Asia since May 1998, and more recent fighting in Jammu and Kashmir between India and Pakistan, are relevant to this proposed IPPA.
- 2.32 In May 1998, India and Pakistan conducted a number of tests of nuclear weapons and, earlier in 1999, they carried out tests of intermediate-range ballistic missiles. Beginning late last month, the most serious clashes for some years occurred between the two countries' forces in Kashmir.
- 2.33 The visit by the Indian Prime Minister to his Pakistan counterpart in Lahore in February 1999 was seen by DFAT as leading to 'a degree of cautious optimism' about the bilateral relationship. The Pakistan Prime Minister was to return this visit in due course. Particularly after the tests in 1998, this was indeed a hopeful sign. 15

¹¹ A-IBC, Submission, p. 1

¹² Unless specified otherwise, material in previous sections was drawn from the NIA for the IPPA with India, p. 3.

¹³ Franca Musolino (AGs), Transcript of Evidence, 31 May 1999, pp. TR 19-21

¹⁴ Glenda Gauci (DFAT), Transcript of Evidence, 31 May 1999, p. TR 23

¹⁵ Exhibit No 1, p. 2. Neither nation allowed these issues to have any impact on their participation in the World Cup Cricket, held in the United Kingdom in May–June 1999.

- 2.34 Both nations continue to maintain publicly that they gathered sufficient data from their 1998 tests to justify their moratoriums on further testing. Both nations have also indicated that they will sign the Comprehensive Test Ban Treaty (CTBT) in 1999. Their strategic weapons programs continue to enjoy strong domestic support.¹⁶
- 2.35 In commenting on an IPPA with Pakistan, its tests in response to India's actions were described in our *Fifteenth Report* as adding 'a considerable irritant' to the bilateral relationship with Australia.¹⁷
- 2.36 Following those tests in May 1998, Australia imposed a range of measures against both India and Pakistan, to demonstrate clearly the depth and strength of this country's concern. These measures consisted of a suspension of contacts by Ministers and senior officials, the suspension of non-humanitarian development assistance, and the suspension of defence relations. Australian government policy ruled out taking any measures that impacted negatively on the bilateral economic and commercial relationships. To have taken such measures would have unfairly and disproportionately injured, or potentially injured, Australian companies.
- 2.37 Since the imposition of these measures, DFAT said that from December 1998 there had been 'some encouraging movement', from both India and Pakistan, to comply with certain of the elements of the United Nations' Security Council resolution about their tests. As a result, the suspension of visits by Australian Ministers and senior officials had been relaxed. The Government continues to urge both nations to move more quickly and substantively to adhere to international norms of behaviour on disarmament and nuclear proliferation issues, such as by early signature of the CTBT. Australia's general encouragement of both nations would continue.¹⁸

Conclusion and recommendation

- 2.38 Nuclear testing and fighting in Kashmir are not issues central to the IPPA with India, but they have had their impacts on Australia's relationships with both India and Pakistan.
- 2.39 There are good reasons why both nations wish to distract their people from internal affairs at this time: a caretaker regime in India until national

¹⁶ Exhibit No 1, p. 1. See The Australian Financial Review, 13 May 1999, p. 17, and 26 May 1999, p. 12

¹⁷ JSCT, Fifteenth Report, June 1998, p. 58

¹⁸ Unless specified otherwise, material in this section was drawn from Transcript of Evidence, Glenda Gauci (DFAT), 31 May 1999, pp. TR18, 19.

elections later in the year, accusations of corruption against senior politicians in Pakistan. It is hardly surprising that use has been made, on both sides, of the powerful issue of Kashmir. Reports that war over the disputed territory 'could not be ruled out' do not support hopes for a speedy end to the present fighting.¹⁹

- 2.40 Continuation of the fighting in Kashmir is not a useful contribution to Australia's relationship with either India or Pakistan. It is to be hoped that the cooperative spirit which seemed to be emerging after the talks in Lahore earlier in 1999 can be found again.
- 2.41 The proposed IPPA with India will assist in the further development of what is already a very important trade and investment relationship for both countries. The text departs from the Australian model in ways that meet India's needs, but it does not seem that these changes will prejudice Australian interests. If this were to occur, consideration would have to be given to re-negotiation.

Recommendation 1

The Committee supports the proposed *Agreement on the Promotion* and *Protection of Investments with India*, and recommends that binding treaty action be taken.

Proposed Investment Promotion Agreement with Lithuania

Reasons for the proposed treaty action

2.43 Since 1996, Lithuania has been receiving increased inward investment. The commitment shown by its Government to foreign investment promotion, the continuing improvement in its economy and a number of strategic factors make Lithuania an attractive investment destination.

- 2.44 Lithuania is drawing interest from Australia's small and medium-sized enterprises which view that country as a test market and a strategic location for expanding operations into markets in Central Europe, the Commonwealth of Independent States (CIS) and Russia. Lithuania is also one of the Central and Eastern European candidates for membership of the European Union (EU).
- 2.45 The proposed Agreement is seen as a logical way for Australia to stimulate the flow of investment between this country and Lithuania. It will put Australian investors in a better position to benefit from the opportunities becoming available in Lithuania, by providing them with a range of guarantees relating to non-commercial risk.²⁰

Australia's relationships with the Baltic States

- 2.46 In information provided after the hearing, DFAT drew attention to a number of additional points about the proposed Agreement.
- 2.47 Australia's decision, in the early 1990s, to negotiate IPPAs and like agreements with former Soviet bloc countries was political in nature. It represented a desire to be responsive to these countries and their view that such agreements would assist their economic and political transition. Trade and Economic Cooperation Agreements were therefore concluded with the Baltic states in the early-to-mid 1990s.²¹
- 2.48 These countries usually profess to see in such Agreements the potential for providing a more reliable basis for the conduct of commercial relations between themselves and the other partner. DFAT has accepted that IPPAs may help to smooth the way for Australian companies pursuing commercial opportunities.
- 2.49 The combination of such factors as Lithuania's prospective membership of the EU, the various economic reforms undertaken there, and the presence in Australia of a significant number of people of Lithuanian descent all strengthened the case for the proposed IPPA.
- 2.50 Current resource constraints preclude DFAT treating Latvia and Estonia as priority countries for the negotiation of IPPAs and DTAs. If these countries were to accept the Australian Model IPPA text, consideration might be given to negotiations.

²⁰ Material in this section was drawn from the NIA for the *Proposed IPPA with Lithuania*, hereafter NIA for the IPPA with Lithuania, p. 1, and *Transcript of Evidence*, Robert Walters, (DFAT), 31 May 1999, p. TR1.

²¹ Robert Walters (DFAT), Transcript of Evidence, 31 May 1999, p. TR9

2.51 The Australian Embassy in Sweden is accredited to the Baltic States, each of which also has its own Honorary Australian Consul. Austrade's representation in these countries is provided from Warsaw.²²

Australia-Lithuania trade and investment

- 2.52 In 1997, Lithuania exported \$A7.6 million worth of goods to Australia. In 1998, Australia's exports amounted to \$A9.6 million, made up principally of butter, wool and in earlier years, raw hides and skins. For investments, areas of potential interest would be in transport and communications, as well as in agriculture.²³
- 2.53 Austrade has advised that, while Australian investment in Lithuania is negligible, investment is expected to flow there if an IPPA is in place. Lithuania has the largest population of the Baltic States and is an attractive base for adjacent markets in that region.²⁴

Obligations imposed by the proposed treaty action

- 2.54 The proposed Agreement would establish a clear set of obligations relating to the promotion and protection of investments, in accordance with each Party's laws, regulations and investment policies. While there are a few minor changes, the proposed IPPA does not differ substantially from the Australian Model text.²⁵
- 2.55 Compliance with the proposed IPPA has few foreseeable direct financial costs for Australia.

Date of binding treaty action

2.56 The proposed Agreement shall enter into force 30 days after, the date on which the Parties have informed each other that their Constitutional requirements for its entry into force have been fulfilled. It is proposed that Australia's notification to this effect be passed to the Lithuanian Government after 9 August 1999.²⁶

²² Unless specified otherwise, material in this section was drawn from *Transcript of Evidence*, 31 May 1999, Robert Walters (DFAT), p. TR9, and from DFAT *Submission No 3*, pp. 2-3.

²³ DFAT, Submission No 3, p. 4; Robert Walters (DFAT), Transcript of Evidence, 31 May 1999, p. TR15

²⁴ DFAT, Submission No 3, p. 3

DFAT, Submission No 3, pp. 1-2; Robert Walters (DFAT), Transcript of Evidence, 31 May 1999, p. TR4

²⁶ NIA for the IPPA with Lithuania, p. 1

Consultation

- 2.57 No comments were received from the States and Territories, following presentation of the text of the proposed IPPA to SCOT.
- 2.58 DFAT sent the Australian-Lithuanian Chamber of Commerce (A-LCC) a copy of the draft text, but no comments were received. The Chamber forwarded a submission to this inquiry, noting that the proposed Agreement provided a clear statement of principles to protect investments, and to provide rules to govern investments, by and in both countries.²⁷

Withdrawal

2.59 If ratified, this IPPA would remain in force for an initial period of 15 years, and after that would remain in force indefinitely unless one of the Parties gave one year's written notice of termination. The Agreement would continue to be effective for a further period of 15 years from the date of termination for investments made or acquired before that date.²⁸

Evidence presented

- 2.60 In addition to matters discussed elsewhere in this consideration of the proposed Agreement, at the public hearing we took evidence:
 - on the cost to Australia of arbitrations under the proposed Agreement that could be referred to ICSID:²⁹
 - that normal provisions were included in the proposed IPPA dealing with investments made before it entered into force;³⁰ and
 - on the cost of negotiating the proposed Agreement.³¹
- 2.61 The Attorney-General's Department (AGs) advised that there has been no arbitration involving Australia brought by an international investor under an IPPA. Nor has Australia taken action against another State with which it has concluded such an Agreement.³²

²⁷ A-LCC, Submission No 1, p. 1

²⁸ Unless otherwise specified, material in the above sections was drawn from the NIA for the IPPA with Lithuania, pp. 1-2.

²⁹ Bill Campbell and Franca Musolino (AGs), Transcript of Evidence, 31 May 1999, pp. TR4-5

³⁰ Bill Campbell and Franca Musolino (AGs), Transcript of Evidence, 31 May 1999, pp. TR5-7

³¹ Robert Walters (DFAT), Transcript of Evidence, 31 May 1999, pp. TR7-8

³² AGs, Submission No 2, p. 1

2.62 DFAT was not able to give a specific figure for the cost of negotiating the proposed IPPA since 1995, but most of these negotiations were carried out by correspondence. A Lithuanian delegation visited Canberra in May 1995 for the only round of face-to face negotiations. This involved DFAT and AGs officials in some preparatory work. Over the past two and a half years, the Australian Embassy in Stockholm has spent about four days working on this matter. The former Embassy in Copenhagen, previously accredited to Lithuania, also spent a day on the proposed IPPA.³³

Committee comments

- 2.63 Although Australia and Lithuania have close links, the amount and range of two-way trade is not significant. While Lithuania's location obviously favours close contact with markets in the CIS, Russia and Central Europe, it is far from clear that it is the only or the best strategic location for this work.
- 2.64 It was made clear that this proposed Agreement was entered into for political reasons. It is clearly important to establish close economic ties with countries that have emerged from the former Soviet Union. Negotiation of the proposed IPPA with Lithuania will extend the economic relationship with Australia. Given the existing small amount of trade and investment, it is unlikely to have a significant impact even in the medium term.
- 2.65 If the proposed Agreement was largely political in nature, the cost of negotiating IPPAs with the other Baltic States must be considered, particularly at a time of resource constraints. These three nations often seem to be treated as a unit, however, even if in fact they are separate nations. It does not seem to be sensible to treat one of them in a different way to the other two.
- 2.66 We are concerned by the amount of additional information that had to be provided after our public hearing on 31 May 1999. Material on some significant matters was not available at that hearing. Some of this was basic to the proposed Agreement, or would have provided useful background information at that time. It should all have been in the NIA, or given in response to questions.

Conclusion and recommendation

2.67 The proposed IPPA with Lithuania is a means of ensuring an Australian trade and investment presence in that country, even if little benefit will be seen for some time. Because of the close relationships between the Baltic States, negotiation of IPPAs with Latvia and Estonia should be pursued as soon as practicable.

Recommendation 2

2.68 The Committee supports the proposed *Agreement on the Promotion* and *Protection of Investments with Lithuania*, and recommends that binding treaty action be taken.

Proposed Trade and Economic Relations Agreement with Fiji

Reasons for the proposed treaty action

- 2.69 Australia wishes to promote and expand mutually beneficial trade and economic cooperation with Fiji. The purpose of the proposed Agreement is to strengthen and diversify the comprehensive trade, investment and economic relationship between the two countries. Once in force, it will serve as an umbrella under which specific bilateral economic and trade activities can be put in place to support the strengthening of the trade and economic relationship. These could be formalised through MOUs.
- 2.70 Such activities could include institutional strengthening in specific sectors, such as textiles, clothing and footwear and agriculture, promotion and protection of investment, trade promotion, commodity trade and trade facilitation.
- 2.71 Bilateral trade in goods and services reached \$A1.1 billion in 1998. The two-way trade in goods and services amounted to \$A866 million, of which \$A528 million was Australian exports to Fiji. The two-way trade in services was estimated at about \$A240 million.

- 2.72 While Australia is Fiji's major market for manufactured goods, Fiji is an important market for Australia's value-added products and for small to medium enterprises, many of which are new to exporting. Australia's share of the market is 48 per cent, and a significant Australian-based commercial infrastructure is in place to service it.
- 2.73 The latest (1996) statistics indicated that Australia's investment in Fiji totalled some \$A577 million, but DFAT estimated the total value of Australia's commercial infrastructure in Fiji at twice that level.

Obligations imposed by the proposed treaty action

- 2.74 The proposed Agreement is designed to give effect to agreed activities intended to foster the bilateral trade and economic relationship. Subject to their laws, regulations and investment policies, the proposed Agreement requires the Parties to take all appropriate measures to strengthen and diversify their trade, economic relations and investment, including:
 - facilitation of investment;
 - negotiation of commercial contracts;
 - development of industrial and technical cooperation;
 - exchanging commercial and technical representatives; and
 - holding trade fairs and other promotional activities that advance trade.
- 2.75 No additional costs are expected to arise from the entry into force of the proposed Agreement. Costs for the regular Ministerial meetings referred to in Article 8 will be met from existing budgets.

Date of binding treaty action

2.76 The proposed Agreement shall enter into force on the date on which the Parties have informed each other that their internal legal procedures for bringing it into force have been completed. It is proposed that Australia's notification to that effect be lodged after 9 August 1999.³⁴

³⁴ Unless specified otherwise, material in the above sections was drawn from the NIA for the Proposed Trade and Economic Relations Agreement with Fiji, hereafter NIA for the Trade Agreement with Fiji, pp. 1-2,. and Transcript of Evidence, 31 May 1999, Colin Hill (DFAT), pp TR 26-27.

Consultation

- 2.77 The States and Territories were advised of the proposed Agreement through the SCOT process, and no comments were made.³⁵
- 2.78 The Australia-Fiji Business Council (A-FBC) was consulted about the proposed Agreement and 'warmly supported' it as a mechanism to broaden the agenda for developing the bilateral economic relationship.
- 2.79 In a submission to this inquiry, the Council congratulated the Australian Government on its initiative in negotiating this treaty with its most important trading partner in the Pacific Island countries. It added that the proposed Agreement was a recognition of the importance of the bilateral relationship between the two countries, in particular the depth of their trade and commercial ties.
- 2.80 The Council noted that trade between Australia and Fiji was 'substantially more valuable than some other countries and country groups that have a higher profile in the (Australian) Government's export support programs'. Australia is Fiji's major market for manufactured goods, while Fiji is an important export destination for many small- to medium-sized Australian manufacturing companies across a range of industries.
- 2.81 It pointed out that, while the nature of offshore investment made it difficult to quantify, Australian investment in Fiji's commercial infrastructure was substantial and had been estimated as in excess of \$A1 billion. The Council believed that concluding the proposed Agreement could only improve Australia's standing as Fiji's major trading partner. It would also provide a new framework which would help to protect Australia's commercial interests there.³⁶
- 2.82 At the public hearing on 31 May 1999, the Council's Executive Director endorsed the proposed Agreement as another step in providing opportunities for further developing a long and substantial commercial and economic relationship. Mr Yourn also pointed out that Australia's interests in Fiji rely upon a strong and healthy economy. He thought that the relationship had sufficient elements to support the developments sought by the proposed Agreement.³⁷

³⁵ $\,$ NIA for the Trade Agreement with Fiji, p. 2

³⁶ Unless otherwise specified, material in this section was drawn from A-FBC's submission.

³⁷ Frank Yourn (A-FBC), Transcript of Evidence, 31 May 1999, p. TR 28

Withdrawal

2.83 Article 12 of the proposed Agreement provides that it will be in force for an initial period of five years, after which either Party may terminate it by 12 months' written notice of its intention to withdraw from it.³⁸

Evidence presented

- 2.84 In addition to other matters discussed elsewhere in this review of the proposed Agreement, at the public hearing we also took evidence on discrepancies between figures provided for Australian investment in Fiji.³⁹
- At that hearing, there was also some discussion of the likely implications of the recent election in Fiji for the proposed Agreement. A later newspaper report referred to 'potentially serious problems' if the Fijian Government faltered in addressing the key economic issues: land tenure, reform of the sugar industry and job creation. It noted that while the Government's responses to these issues was as yet unclear, there were no indications that Australia could not continue to do good business with Fiji.⁴⁰

Conclusion and recommendation

- 2.86 Two-way trade between Australia and Fiji is of a sufficient volume and variety that a Trade and Economic Relations Agreement is probably overdue. It will undoubtedly provide a framework within which that relationship can grow.
- 2.87 The whole-hearted support of the Australia-Fiji Business Council for the overall relationship, and the proposed Agreement in particular, was clear from well before the beginning of this inquiry. The involvement of such an active group bodes well for the future of the trade and investment relationship. It must also be recognised that the newly-elected Government of Fiji is confronted by a range of difficulties and that its actions will contribute to the success, or otherwise, of the proposed Agreement.

³⁸ NIA for the Trade Agreement with Fiji, p. 2

³⁹ Stephen Hill (DFAT), Transcript of Evidence, 31 May 1999, p. TR27

⁴⁰ Colin Hill (DFAT), *Transcript of Evidence*, 31 May 1999, p. TR28. See *The Courier Mail*, 8 June 1999, p. 27.

Recommendation 3

2.88 The Committee supports the proposed *Trade and Economic Relations*Agreement with Fiji, and recommends that binding treaty action be taken.

Proposed amendments to the World Health Organization's Constitution

The World Health Organization and its Executive Board

- 3.1 The World Health Organization (WHO) was established for the purpose of cooperating to promote and protect the health of all peoples. It acts as the directing and coordinating authority on international health work with the objective of the 'attainment by all peoples of the highest possible level of health'.
- 3.2 WHO's Constitution entered into force in 1948 and under its provisions the Executive Board, together with the World Health Assembly (WHA) and the Secretariat, carries out the work of WHO.
- 3.3 The Executive Board serves as the executive arm of the WHA. Seats on the Board are allocated to achieve an equitable geographic distribution between member countries across the following regions:
 - Africa;
 - the Americas;
 - Europe;
 - the Eastern Mediterranean;
 - South-East Asia; and
 - the Western Pacific.
- 3.4 The WHA elects the allocated number of member countries from each of these regions. Each of these countries so elected is then entitled to designate a suitably qualified person to serve on the Board. It is this body

- that gives effect to the Assembly's decisions and policies, submitting work programs and preparing the agenda for WHA meetings.
- 3.5 Executive Board members represent their countries for three years. Those appointed should be technically qualified in the field of health.¹

Proposed treaty action

- 3.6 The proposed amendments to Articles 24 and 25 of the Constitution of WHO were adopted at the 1998 WHA meeting to redress the imbalance in Board membership caused by an increase of member countries in the European and the Western Pacific regions.
- 3.7 Articles 24 and 25 have been amended on a number of previous occasions, increasing the size of the Board from an original 18 members to the present 32. All previous amendments to these numbers, the last in 1986, have been accepted by Australia.
- 3.8 The 1998 amendments followed a detailed review of the formula used to allocate seats on the Board. The change proposed to Article 24 would increase membership of the Board to 34. The allocation of seats on that Board from the European region will then be increased from seven to eight, and the Western Pacific region's allocation from four to five.
- 3.9 A consequential amendment has been made to Article 25 to reflect this increase to Board membership.
- 3.10 These amendments relate to the internal organisation of WHO and are minor in nature.²

Obligations imposed by the proposed treaty action

3.11 These amendments to the WHO Constitution will not add to Australia's existing obligations. Under the *World Health Organization Act 1947*, Australia has undertaken to act on conventions or agreements adopted by the WHA. Under Article 19 of that Constitution, such conventions would require a two-thirds vote and acceptance by members to come into force. To date, no such treaties have been adopted.

¹ Unless otherwise specified, material in this section was drawn from the National Interest Analysis (NIA) for the *Proposed Amendments to the WHO Constitution*, (hereafter NIA for the WHO Constitution), p. 2.

² Unless otherwise indicated, material in this section was drawn from *Transcript of Evidence*, Bob Eckhardt (Health and Aged Care), 31 May 1999, p. TR29.

3.12 The proposed treaty action will not impose any additional costs on Australia. The cost of two additional Executive Board members would have a negligible impact on WHO's \$US1.6 billion annual budget, and on Australia's contribution which for 1999 is \$A9.611 million. Contributions to WHO are based on the population of the member country.³

Date of binding treaty action

3.13 These amendments proposed to Articles 24 and 25 of its Constitution will come into force for all members when they have been accepted by two-thirds of WHO's members. It is proposed that Australia's Instrument of Acceptance be lodged with the Secretary-General of the United Nations after 9 August 1999.⁴

Consultation

3.14 The proposed amendments were advised to the States and Territories through the SCOT process. They do not have any direct effect on the States and territories.

Withdrawal

3.15 These 1998 amendments do not provide for withdrawal or denunciation nor does the head Agreement, the WHO Constitution. It is possible to withdraw from WHO at any time by consent of all parties, as provided for by Article 54 of the Vienna Convention on the Law of Treaties.⁵

Benefits to Australia

- 3.16 The benefits to Australia from its membership are derived from WHO's normative health functions. It sets international standards for environmental health, chemical safety, nomenclature of health terms and common data definition of health procedures.⁶
- 3.17 Australia is a member of the Western Pacific region, currently represented by the Peoples' Republic of China, the Peoples' Democratic Republic of Laos, Kiribati and the Cook Islands. The proposed amendments to WHO's

³ NIA for the WHO Constitution, p. 2; Bob Eckhardt (Health and Aged Care), Transcript of Evidence, 31 May 1999, pp. TR29-30

⁴ NIA for the WHO Constitution, p. 1

⁵ Unless otherwise specified, material in the above sections was drawn from the NIA for the WHO Constitution, p. 3

⁶ Bob Eckhardt (Health and Aged Care), Transcript of Evidence, 31 May 1999, p. TR 30

Constitution would increase that region's influence on the Executive Board and, as a result, on the administration of WHO itself. This country was last represented on the Executive Board until 1996.7

Conclusion and recommendation

Recommendation 4

3.18 The Committee supports the proposed *Amendments to Articles 24 and 25 of the Constitution of the World Health Organization*, and recommends that binding treaty action be taken.

⁷ Bob Eckhardt (Health and Aged Care), Transcript of Evidence, 31 May 1999, p. TR29

Proposed MRA with Iceland, Liechtenstein and Norway

Mutual recognition agreements

- A mutual recognition agreement (MRA) is a treaty through which Australia and other Parties recognise that Conformity Assessment Bodies (CABs) designated by each other are competent to test and certify a specified range of products to meet their domestic regulatory requirements.
- 4.2 There is often a requirement that goods for export and subject to mandatory technical regulations in a Party, need to be tested and/or certified for compliance with regulatory requirements by a body in the importing country. MRAs enable conformity assessment, that is: the testing, inspection and certification, of products intended for sale in the other Party's territory, to be undertaken in the country of origin.
- 4.3 Such agreements generate substantial reductions in non-tariff barriers by enabling Australian producers to manufacture products and have them fully assessed for conformity to the standards and legal requirements of the other Party in this country prior to export. Economies of scale are offered by the opportunity to have products assessed by the same CABs for both domestic and export markets covered by MRAs at the same time. Exporters will be able to avoid delays and higher costs arising from the current requirement for conformity assessment to be carried out in the importing country.
- 4.4 Technical barriers to trade, such as differences in standards, technical requirements or conformity assessment regimes, can present significant barriers to trade. One estimate suggested that they can add between 2 and 10 per cent to the cost of making and exporting a product. Under current

- arrangements, three tests would probably be required to export goods to Iceland, Liechtenstein and Norway. Under the proposed MRA, one test in Australia would suffice.¹
- 4.5 MRAs provide an alternative mechanism for meeting other countries' requirements, but they are not the only means available. Australian manufacturers can still choose to have their products assessed in the importing country by one of its CABs.²
- 4.6 The Department of Industry, Science and Resources (DISR) stated that negotiation of MRAs was a significant trade facilitation measure and consistent with Government trade objectives. Provisions of the MRA were consistent with the approach to conformity assessment taken in the World Trade Organisation (WTO) Agreement on Technical Barriers to Trade Agreement. Article 6.3 encourages Members to be willing to enter into negotiations for the mutual recognition of the results of each other's conformity assessment procedures. Australia is a Party to that Agreement.
- 4.7 The principle behind this WTO 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 has been put in place, the implementing country has to identify what is known as 'a legitimate objective'. While this is not defined in the WTO Agreement, human health and safety are often used as such objectives. In most cases, if the technical regulation flows directly from an international standard, it is assumed that it conforms with the WTO Agreement.³
- 4.8 Australia is leading the way in the development of bilateral MRAs: that with the European Union (EU) was 'the first fully operational' MRA in the world.
- 4.9 MRAs do not result in new regulations, nor will they address differences in standards. They provide alternative mechanisms for importers and exporters to comply with existing regulatory requirements of the other Party, while avoiding additional delays and costs. For information technology products with relatively short marketing lives, delays for testing and certification in the importing country can have severe impacts on marketing.
- 4.10 Savings via an MRA provide the potential for consumers to benefit from lower prices and a wider range of choice through cheaper costs for

¹ Guy Wilmington (DSIR), Transcript of Evidence, 7 June 1999, pp. TR37, 40, 41, 37

² Guy Wilmington (DSIR), *Transcript of Evidence*, 7 June 1999, p. TR32

³ Mark Hillis (DFAT), Transcript of Evidence, 7 June 1999, p. TR39

importers. Economies of scale are also created by having products assessed at the same time by the same CABs for both domestic and export markets.

Other advantages of MRAs

- 4.11 Other advantages of MRAs include:
 - provision of legal certainty that further conformity assessment will not be needed in the importing market;
 - removal of conformity assessment as an instrument of industry policy;
 - reduction of the risks of using conformity assessment as a means of reverse engineering and other illicit forms of technology transfer;
 - devolution of conformity assessment to stimulate competition and enhance the technological base of an economy, and
 - enhancement of the transparency of regulatory regimes, and promotion of longer term objectives of harmonising standards and technical regulation.⁴

MRA with the European Community

- 4.12 In its *Fifteenth Report*, the previous Committee commented on the MRA with the EU.⁵
- 4.13 In its Report, that Committee noted that there were complications in considering that proposed Agreement. At the time of tabling the text and the NIA for the MRA with the EU, formal endorsement of the proposal by Queensland was outstanding. There were also a number of matters that needed further examination, including criticism of Article 4 of that Agreement. This precludes the assessment of products not originating in the territories of the Parties, and presents particular difficulties for some Australian companies because many of their products are assembled from materials that originate elsewhere.
- 4.14 The Report noted that material from the then Department of Industry, Science and Technology (DIST) pointed out that Australian negotiators

⁴ Material in the above sections was drawn from the National Interest Analysis (NIA) for the proposed *Mutual Recognition Agreement with Iceland, Liechtenstein and Norway*, (hereafter NIA for the MRA with EFTA), pp. 1, 2-3. See also Guy Wilmington, (Department of Industry, Science and Resources, hereafter DISR), *Transcript of Evidence*, 7 June 1999, p. TR32.

Joint Standing Committee on Treaties, 38th Parliament, Fifteenth Report, June 1998, (hereafter JSCT, 15th Report), pp. 64-66. That Report was tabled on 2 July 1998.

- had opposed the inclusion of this provision since the commencement of negotiations in 1994. DIST stated that its understanding of the EU rules would allow certain products to be classed as originating in Australia. The Committee did not consider 'such an equivocal statement' to be satisfactory and believed that it needed to explore that Agreement further.
- 4.15 Written material supplied by DIST noted that it shared concerns expressed by ElectroMagnetic Compatibility and Systems Integration Pty Ltd (EMCSI) 'about the inequity' of the situation caused by Article 4 of the text. The Department stated that it would be seeking to have that Article removed from the Agreement, and noted that agreements with the USA and Canada did not contain this provision.
- 4.16 With these unresolved issues and incomplete evidence, the previous Committee was not able to conclude its consideration of the proposed MRA with the EU.
- 4.17 In *Report 20*, following further consideration of the matter, this Committee supported that Agreement noting that it would help simplify procedures faced by Australian companies seeking to export to the European market.⁶
- 4.18 We found, however, that the quality and timeliness of the information provided by DIST was not satisfactory, and had delayed finalisation of our consideration of the matter. We expressed concern about the accuracy of the understanding by DIST of the EU's rules of origin. We trusted that the efforts of Australian companies seeking to export goods assembled in this country from imported goods would not be hampered by these new arrangements.
- 4.19 Finally, that Report noted that binding treaty action had already taken place, and that mutual recognition procedures with the EU were already in place. This MRA came into force on 1 January 1999 after an Exchange of Notes between the Australian Government and the EU.

Delays in implementing the MRA with the EU

4.20 In fact, as a recent letter from the Minister for Industry, Science and Resources made clear, the entry into force of the MRA with the EU was not as smooth as it might have been.

⁶ JSCT, 39th Parliament, *Report 20*, March 1999, pp. 9-11, (hereafter JSCT, Report 20). That Report was tabled on 29 March 1999.

JSCT, Report 20, p. 11; Exhibit No 1, Minister for Industry, Science and Resources letter, dated 25 May 1999, (hereafter Ministerial letter), p. 1. Guy Wilmington (DISR), *Transcript of Evidence*, 7 June 1999, p. TR32.

- 4.21 While this Agreement was signed on 24 June 1998, there were considerable delays in finalising it. There was a need to obtain the signatures of all the States and Territories to an Inter-Governmental Agreement (IGA). A number of sectors covered by the MRA with the EU are regulated at the State/Territory level.
- 4.22 The Minister's letter continued that, unfortunately, full implementation of this MRA was again delayed following entry into force on 1 January 1999 while the European Commission sought the agreement of its Member States to Australian CABs. He noted that the necessary administrative procedures needed to make the MRA with the EU fully effective had been put in place.
- 4.23 DISR and the European Commission had formally agreed to the initial lists of CABs to operate under that MRA. CABs in all the sectors it covered are now able to undertake the assessment of products in Australia, prior to export to the European market. If health-related products have already been assessed here by the Therapeutics Goods Administration (TGA) for compliance with the European Commission's regulatory requirements, they can now placed in that European market without further testing.⁸

MRA with Iceland, Liechtenstein and Norway

- 4.24 Iceland, Liechtenstein and Norway are members of the European Free Trade Association (EFTA). For reasons of sovereignty, they are not members of EU and therefore cannot be Parties to the MRA with that body.
- 4.25 These three countries also form part of the European Economic Area (EEA) and their participation is governed by an agreement between EFTA and the EU. That agreement requires the EFTA states to use European regulations or directives as the basis of their regulation. It also states that where the EU negotiates an MRA with a third country, it does so on the basis that that third country will conclude an equivalent agreement with Iceland, Liechtenstein and Norway. Having negotiated an MRA with the EU, Australia was 'morally bound' to negotiate a similar agreement with these three members of EFTA.

⁸ Exhibit No 1, Ministerial letter, p. 1. The TGA is a Division within the Department of Health and Aged Care. Under the *Therapeutic Goods Act 1989*, it is responsible for the regulation of therapeutic goods manufactured in, imported into or exported from Australia. Therapeutic goods include products such as medicines, pharmaceutical medicines, over-the-counter medicines, as well as complementary medicines and medical devices. Rita Maclachlan (TGA), *Transcript of Evidence*, 7 June 1999, p. TR34.

- 4.26 While the proposed Agreement has been negotiated by Australia with Iceland, Liechtenstein and Norway, in effect it remains a bilateral agreement with those three countries acting as one Party. No single country can withdraw from the proposed MRA without it becoming inoperative. DISR assessed the possibility of this occurring as 'very low'. Because of their ties to the EU, withdrawal would be more detrimental to the three EFTA members than to Australia.
- 4.27 Negotiation of an MRA with these countries will provide additional benefits at minimal cost by extending the number of countries to which such an Agreement applies. Since regulations for EFTA members are identical to those that apply within the EU, Australian CABs will not have to incur any additional cost or burdens in being designated under the proposed Agreement.
- 4.28 There is a small component of Australia's trade with the EEA currently denied the benefits that flow from the MRA with the EU. In conjunction with that Agreement, the proposed MRA will ensure that uniform conformity assessment provisions apply to all regulated products covered by these Agreements. It will facilitate, therefore, free movement of Australian goods between all EEA countries.
- 4.29 This MRA will include the following eight product-regulated sectors:
 - electromagnetic compatibility;
 - pharmaceuticals;
 - medical devices
 - telecommunications terminal equipment and automotive products regulated by the Commonwealth in Australia; and
 - pressure equipment, machinery and low voltage equipment regulated by the States and Territories.⁹
- 4.30 In 1998, total merchandise trade between Australia and Norway was \$A403.5 million; between Australia and Iceland, total trade was \$A10.9 million. Australia had a deficit of \$A61.3 million with Norway and a \$A2.3 million surplus with Iceland.
- 4.31 The NIA did not include any details of trade with Liechtenstein because that country shares a common customs service with Switzerland and trade data was combined with that from Switzerland. DISR suggested that there

⁹ Guy Wilmington (DISR), Transcript of Evidence, 7 June 1999, p. TR42

- was potential for increased trade with Liechtenstein under the proposed Agreement.¹⁰
- 4.32 It sets out the general rights and obligations of the Parties. In particular, Annex 1 sets out procedures for the designation, evaluation and monitoring of CABs. Sectoral Annexes of less than treaty status form the basis of the implementing arrangements. They set out the specific requirements about the designation of CABs and the demonstration of compliance with the regulatory requirements in particular product areas. Sectoral Annexes can be amended by the Parties through the Joint Committee, set up under Article 12 of the proposed Agreement.¹¹
- 4.33 The TGA advised that the proposed Agreement would cover good manufacturing practice, inspection of medicinal products, conformity assessment of medical devices, the whole process of assessing a medical device as appropriate for the European market.¹²

Obligations imposed by the proposed treaty action

- 4.34 Once in force, the proposed MRA would oblige Australia's regulators in agreed product areas to accept attestations of conformity, including test reports, certificates, authorisations and where appropriate marks of conformity issued in accordance with Australian requirements by specifically designated CABs in Iceland, Liechtenstein and Norway. In addition, Australia's regulatory authorities will not be able to require further testing of these countries' products covered by the proposed MRA prior to marketing them in this country.
- 4.35 The designated CABs are individually and specifically identified in the Sectoral Annexes. These designations are subject to safeguards that provide a mechanism for withdrawal of designation from any CAB that fails to fulfil its obligations.
- 4.36 All the obligations imposed by the proposed MRA are matched by reciprocal obligations that apply to all the States covered by MRAs.
- 4.37 The TGA advised that, under the proposed MRA, Australian manufacturers will have to meet the regulatory requirements of the EU, and *vice versa*. The text states that the Parties will initiate and undertake harmonisation activities 'to whatever extent is possible'. For therapeutic

¹⁰ Guy Wilmington (DISR), Transcript of Evidence, 7 June 1999, p. TR33

¹¹ Unless otherwise specified, material in this section was drawn from the NIA for the MRA with EFTA, pp. 1, 3. See also Guy Wilmington (DISR), *Transcript of Evidence*, 7 June 1999, pp. TR 32, 33.

¹² Rita Maclachlan (TGA), Transcript of Evidence, 7 June 1999, p. TR34

- goods, the TGA stated, Australia's standards for Good Manufacturing Practice are equivalent to those in the EU and the EFTA countries.¹³
- 4.38 The TGA stated that it was preparing a submission for the Government's consideration about harmonising Australia's regulatory requirements with those of the EU. If this proceeds, it will bring Australian standards into line with international standards. It noted that work is proceeding with the USA, Canada and Japan on the task of global harmonisation, based on the EU's standards, so that the five major jurisdictions will have equivalent regulatory standards.¹⁴
- 4.39 Until Australia's regulatory requirements are harmonised with those of the EU, there will be some duplication of costs. Additional on-site audits can, for some products, be required to meet EU requirements. It is expected that, in the Spring 2000 Session of the Parliament, legislation will have amended Australia's current regulatory requirements for medical devices. 15
- 4.40 The TGA also advised that, for medical devices, Australian requirements and those for the EU can be different. In the case of dental restorative materials, for example, the Australian requirement is a declaration from the manufacturer that a product meets an International Standards Organization (ISO) standard. Products may be tested at any time to ensure that that standard is met. The EU's requirements were described as 'slightly more rigorous' than Australia's, in that the manufacturer has to have technical documentation that has to be reviewed as part of the manufacturing quality system. Australian manufacturers in such fields therefore have to meet higher standards for products to enter the European market.¹⁶
- 4.41 There will be direct costs to representatives of the Commonwealth, State and Territory Governments which participate, where necessary, in the Joint Committee to be set up under Article 12. As it is proposed that most business will be conducted through correspondence, these costs will be minimal and should be covered within DISR's normal appropriations.¹⁷
- 4.42 The proposed Agreement does not oblige the Australian Government to finance the participation of designated CABs in this country or elsewhere in exercises to establish the competence of these bodies.

¹³ Rita Maclachlan (TGA), Transcript of Evidence, 7 June 1999, p. TR35

¹⁴ Rita Maclachlan (TGA), Transcript of Evidence, 7 June 1999, pp. TR35-36

¹⁵ Rita Maclachlan (TGA), Transcript of Evidence, 7 June 1999, pp. TR36, 38, 42

¹⁶ Rita Maclachlan (TGA), Transcript of Evidence, 7 June 1999, pp. TR35, 38, 42

¹⁷ The change from DIST to DISR in the Commonwealth's Administrative Arrangements took place in October 1998.

Implementation

- 4.43 The NIA stated that no amendments needed to be made to existing legislation to implement the proposed Agreement. All its rights and obligations can be accommodated within existing administrative procedures.
- 4.44 Since the NIA had been tabled, DISR had been notified that a minor amendment was required to the *Therapeutics Goods Act 1989*, relating to the definition of CABS. DISR stated that it would re-confirm that all necessary legislative changes have been made before the exchange of notes takes place. It was expected that this would not delay the entry into force of the proposed Agreement.¹⁸
- 4.45 The proposed MRA does not provide for future protocols. However, a series of Joint Declarations of less than treaty status sets out activities that were agreed between the Parties during negotiation of the proposed text.¹⁹

Date of binding treaty action

- 4.46 The proposed MRA was signed on 29 April 1999. Under Article 14, it will come into force on the first day of the second month following the date on which the Parties exchange Notes confirming completion of their respective procedures for entry into force. This exchange of Notes is expected to take place as soon as practicable after 9 August 1999.²⁰
- 4.47 To make the proposed MRA fully operational, it will be necessary for Australia to designate CABs whose test reports, certificates and/or markings will be recognised by the regulatory agencies in the EFTA states. As they adopt EU directives, this process is expected to be little more than a 'rubber stamping' activity by the EFTA states. In addition, a number of Australian CABs have already demonstrated their competence to test to these requirements by virtue of their designation under the Australia-EU MRA.²¹

Consultation

4.48 States and Territories were advised of the proposed Agreement through the SCOT process and were consulted, with their agreement sought, on developments in the negotiations in areas of their regulatory

¹⁸ Guy Wilmington (DISR), Transcript of Evidence, 7 June 1999, pp. TR33-34

¹⁹ NIA for the MRA with EFTA, p. 5

²⁰ NIA for the MRA with EFTA, p. 1

²¹ Guy Wilmington (DISR), Transcript of Evidence, 7 June 1999, p. TR 34

- responsibility. Regulatory authorities were directly involved in the negotiation of some Sectoral Annexes.
- 4.49 The IGA, concluded and signed by all State and Territory Governments, formalises the coordination of Australia's implementation of the proposed MRA. This IGA will ensure that the States and Territories are able to participate fully in the administration of the proposed MRA.²²
- 4.50 When Australia first entered into negotiations with the EU about an MRA, the TGA consulted Australian industry with a view to 'raising the bar' here. The NIA stated that a wide range of industry groups was fully appraised of developments in those negotiations, and invited to participate in the process as observers. ²³
- 4.51 During negotiation of the proposed Agreement, testing bodies raised the same concerns about Article 4 that were raised in connection with the MRA with the EU: the limitation of the benefits of the proposed Agreement to products manufactured in Australia and New Zealand. They sought a broadening of its scope to include all products tested in Australia, regardless of their origin.

Withdrawal

4.52 Under Article 14(2) of the proposed Agreement, either Party may terminate it by giving the other Party six months' written notice of its intention to do so.²⁴

MRAs and Switzerland

- 4.53 Switzerland is not covered by the MRA with the EU, nor will it be covered by the proposed Agreement with the three EFTA countries. It is part of EFTA but is not a party to the European Free Trade Agreement and, consequently, Australia is not bound to negotiate an MRA with Switzerland. There was one meeting with Swiss officials on the margins of the negotiations for the MRA with the EU. Switzerland has yet to indicate formally any interest in negotiating such an agreement with Australia.
- 4.54 It was DISR's understanding that, for all practical purposes, the lack of an MRA will not present any practical problems for Australian exporters into Switzerland. Swiss regulatory authorities will accept 'Conformity

 $^{\,}$ 22 $\,$ Guy Wilmington (DISR), Transcript of Evidence, 7 June 1999, p. TR 33 $\,$

²³ Rita Maclachlan (TGA), Transcript of Evidence, 7 June 1999, p. TR 35

²⁴ Unless specified otherwise, material in the previous sections was drawn from the NIA for the MRA with EFTA, pp. 3, 4, 5, 6-7.

- European' (CE) marked goods, regardless of their origin. With MRAs with the EU and the three other EFTA countries, access to Switzerland for Australian goods would also be achieved.
- 4.55 Switzerland may wish to gain access to Australian markets on similar terms, or may wish to formalise its understanding through an MRA. DISR stated that such a proposal would be given 'due consideration', but would not be preempted.²⁵

Submissions received

- 4.56 A submission on the proposed Agreement was received from the National Association of Testing Authorities (NATA). It stated that it had been closely involved in the negotiations. Under the MRA with the EU, NATA is a designating authority for five of the eight product sectors. It pointed out that the proposed Agreement is 'complementary to, and essentially the same as' the MRA with the EC that entered into force on 1 January 1999.²⁶
- 4.57 NATA strongly supported the proposed Agreement, seeing it as ensuring a consistent approach in the regulatory environment for all the products exported to/imported from the EEA countries.
- 4.58 A brief submission from the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) also supported the proposed Agreement.²⁷
- 4.59 A letter, treated as a submission, was also received from Nulite Systems International Pty Ltd (NSI). This firm manufactures and markets non-metallic, bio-material dental restoratives and associated products.²⁸

Concerns raised by NSI

- 4.60 Earlier correspondence provided by NSI stated that, in December 1998, its manufacturing systems and products were audited by the TGA, at considerable expense to the firm. NSI was subsequently informed that it had achieved the necessary standards for the European market.
- 4.61 NSI was then issued with a CE number but forbidden to attach it to product packaging, as that number had not been gazetted and approved by the TGA's European counterparts.

²⁵ Material in this section was drawn from *Transcript of Evidence*, Guy Wilmington (DISR), 7 June 1999, pp. TR 32-33.

²⁶ NATA, Submission No 1, p. 1

²⁷ JAS-ANZ, Submission, No 3, p. 1

²⁸ NSI, Submission No 2, p. 1

- 4.62 In its submission, NSI referred to its experiences and 'predictable considerable loss of business, which translated to a considerable financial loss'. It stated that both the TGA and DISR were unprepared for the EC's conformity assessments requirements. This resulted, it continued, in NSI being precluded from trading in the EC until the firm was accredited with a CE marking. It also noted that there were no such restrictions on the importation of goods from the EC. NSI believed that MRA procedures may be in place, but that they are worthless until the whole accreditation package is operating.
- 4.63 NSI asserted that it had received no satisfaction from its attempts to bring this matter to the attention of a number of Ministers, and to the two authorities involved. ²⁹

Evidence on NSI's concerns

- In the context of these claims, the letter from the Minister for Industry, Science and Resources to the Committee Chairman noted that the EC's requirements for the category of medical device made by NSI were 'more rigorous than current Australian requirements'. These more rigorous requirements necessitated an on-site audit of the manufacturer, with resulting additional costs. Such an audit, that letter stated, would not have been necessary to meet Australia's regulatory requirements.³⁰
- 4.65 TGA advised that the manufacturer must meet an acceptable standard of good manufacturing practice, the same standard required in the EU. The particular standard depended on the level of manufacturing systems compliance the manufacturer needs for specific products. NSI's dental restorative materials are required to be listed on the Australian Register of Therapeutic Goods. These products are currently classified as 'low risk , listable products'.³¹
- 4.66 The TGA pointed out that its responsibility was to certify products to European requirements. Other technical barriers to trade in other countries were out of its control.³²

Other evidence received

4.67 At the hearing on 7 June 1999, and in addition to the other matters already included in this Report, we were told that, under the proposed MRA,

²⁹ NSI, Submission No 2, p. 1

³⁰ Ministerial letter, p. 2

³¹ Rita Maclachlan (TGA), Transcript of Evidence, 7 June 1999, p. TR35

³² Rita Maclachlan (TGA), Transcript of Evidence, 7 June 1999, p. TR36

goods from Australia and New Zealand would be treated as if they came from a common exit point. This was a result of the Closer Economic Relations agreement between the two countries.³³

Committee comments

- 4.68 In our consideration of some of the issues that arose during this inquiry, we were conscious that these were perhaps more connected to the MRA with the EU than with the proposed Agreement. We believe that the very close connection between the two matters justifies our dealing with them as if they were one matter.
- 4.69 It is a matter of concern that the MRA with the EU was not fully effective from the date of its entry into force. It is not clear whether DISR or the TGA were at fault in this matter, and it is probably not ascertainable now.
- 4.70 In *Report 20*, we commented about DIST's understanding of the EU's rules of origin, and expressed a hope that the efforts of Australian firms seeking to export goods would not be hampered by the new arrangements. In at least one case, it appears that a misunderstanding of those rules and these arrangements have claimed a victim.³⁴
- 4.71 NSI seems to have followed all the advice it was given in order to obtain the CE marking it needed to export its product, in accordance with the MRA with the EC. Not only did this not happen, but it has also failed to receive any satisfaction from all of the Ministers and authorities it has approached for that purpose. It has lost sufficient money to have decided not to be involved in exporting to the European market in future.
- 4.72 Such an understandable attitude should not be a consequence of agreements such as the proposed MRA. It ironic and regrettable that a firm, seeking to follow Government policies about increasing exports, should find itself in such a position. At very least, it was unfortunate that either the TGA or DISR, or both, did not seem to know that the EC's requirements in NSI's product area were so much more stringent than those in Australia. If they did, it is not clear whether NSI was aware, or made aware, of these different standards and the implications for its products.
- 4.73 Given such facts as the delay in the full implementation of the Agreement, it would not be surprising if other firms had suffered experiences similar

³³ Guy Wilmington (DISR), Transcript of Evidence, 7 June 1999, p. TR41

³⁴ JSCT, Report 20, p. 11

- to those of NSI, although we have not received any information on this matter.
- 4.74 Further than this, we are not able to adjudicate on the claims made by NSI about its treatment. We did not find the information provided by DISR to be wholly satisfactory and, in view of the delays in implementing the MRA with the EU, we are sceptical about some of the timetables given in evidence by DISR and the TGA. This includes the time frame for the necessary amendment to legislation.
- 4.75 At our public hearing, it seemed that both DISR and the TGA were somewhat dismissive of NSI and its position. In this context, we note that the letter from the Minister for Industry, Science and Resources to the Committee Chairman contained interesting and relevant information about the implementation of the MRA with the EU. It did not address, other than in a cursory manner, NSI's concerns which had caused the Chairman's approach.
- 4.76 In two previous Reports from this Committee, a number of concerns were raised about the MRA with the EU. Given the common purpose of that Agreement and the proposed Agreement that was the subject of this inquiry, it is not surprising that concerns about the provisions of Article 4 were raised again. As this proposed MRA is designed to mirror that with the EU, it is unlikely that this provision will be altered when ,as the NIA states, it is raised with Iceland Liechtenstein and Norway.
- 4.77 None of the firms that forwarded submissions to the inquiry raised this matter with us.

Conclusions and recommendation

- 4.78 On the evidence presented to our inquiry, we are satisfied that the proposed MRA with Iceland, Liechtenstein and Norway will benefit Australian manufacturers by reducing the delays and costs of exporting a range of products into the European Economic Area. It would make little sense to have negotiated the MRA with the EU and then leave these three EFTA countries out of the conformity assessment process for the European market.
- 4.79 It seems to us that, to make the MRA process most effective, DISR and the TGA will have to continue their consultation arrangements with Australian industry. These bodies will have to do more to ensure that other firms do not find themselves in the same position as NSI.
- 4.80 It concerns us that the implementation arrangements for the MRA with the EU were not as smooth as predicted. We also note that no additional

- material was presented about the resolution of concerns concerning Article 4 and broadening of the scope of the proposed MRA to cover all products tested in Australia, regardless of their origin.
- 4.81 Finally, we note that, at a comparatively late stage in the process of implementing the proposed MRA, it became clear that an amendment was in fact required to the *Therapeutic Goods Act 1989*. We trust, therefore and for example, that statements about access by Australian goods to the Swiss market are well-founded.

Recommendation 5

4.82 The Committee supports the proposed *Mutual Recognition Agreement* with *Iceland, Liechtenstein and Norway*, and recommends that binding treaty action be taken.

ANDREW THOMSON MP

Committee Chairman

22 June 1999



Appendix A – Extract from Resolution of Appointment

The Joint Standing Committee on Treaties was reconstituted in the 39th Parliament on 9 December 1998.

The Committee's Resolution of Appointment allows it to inquire into and report upon:

- (a) matters arising from treaties and related National Interest Analyses and proposed treaty actions presented or deemed to be presented to the Parliament;
- (b) any question relating to a treaty or other international instrument, whether or not negotiated to completion, referred to the committee by:
 - (i) either House of the Parliament, or
 - (ii) a Minister; and
- (c) such other matters as may be referred to the committee by the Minister for Foreign Affairs and on such conditions as the Minister may prescribe.



Appendix B - Submissions

PROPOSED IPPA WITH INDIA

Submission No Organisation

1 Australia-India Business Council

2 Department of Foreign Affairs and Trade

PROPOSED IPPA WITH LITHUANIA

Submission No
Organisation

Australian-Lithuanian Chamber of Commerce

Attorney-General's Department

Department of Foreign Affairs and Trade

PROPOSED TRADE AGREEMENT WITH FIJI

Submission No Organisation

1 Australia-Fiji Business Council

PROPOSED MRA WITH ICELAND, LIECHTENSTEIN AND NORWAY

Submission No Organisation

1 National Association of Testing Authorities

- 2 Nulite Systems International Pty Ltd
- 3 Joint Accreditation System of Australia and New Zealand



Appendix C - Witnesses at Public Hearings

Monday, 31 May 1999, Canberra

Department of Foreign Affairs and Trade

Richard Rowe, Legal Adviser, Legal Branch, International Organisations and Legal Division

Attorney-General's Department

Bill Campbell, First Assistant Secretary, Office of International Law

Franca Musolino, Principal Legal Officer, International Trade and Environment Law Branch, Office of International Law

Proposed IPPA with India

Department of Foreign Affairs and Trade

Glenda Gauci, Assistant Secretary, Mainland South-East Asia and South Asia Branch

Brett Hackett, Executive Officer, India and South Asia Section

Proposed IPPA with Lithuania

Department of Foreign Affairs and Trade

Rachel Morris, Desk Officer, Europe Bilateral 2 Section, Europe Branch Robert Walters, Director, Europe Bilateral 2 Section, Europe Branch

Proposed Trade Agreement with Fiji

Department of Foreign Affairs and Trade

Colin Hill, Acting Assistant Secretary, Pacific Islands Branch
Stephen Hill, Executive Officer, South Pacific, Africa and Middle East Division
Colin Milner, Executive Officer, Pacific Bilateral Section, Pacific Islands Branch

Austrade

Pat Stortz, Manager, South Pacific

Australia-Fiji Business Council

Frank Yourn, Executive Director

Proposed Amendments to the Constitution of WHO

Department of Health and Aged Care

Bob Eckhardt, Director, International Organisations Section, Policy and International Branch

Monday, 7 June 1999, Canberra

Proposed MRA with Iceland, Liechtenstein and Norway

Department of Foreign Affairs and Trade

Mark Hillis, Executive Officer, Resources/Non-Tariff Barriers

Domaso Marengo, Executive Officer, EU Section

David Mason, Executive Director, Treaties Secretariat

Attorney-General's Department

John Atwood, Acting Assistant Secretary, International Trade and Environment Law Branch, Office of International Law

Franca Musolino, Principal Legal Officer, International Trade and Environment Law Branch, Office of International Law

Department of Industry Science and Resources

Kathryn Hewett, Policy Adviser, Technical and Regulatory Barriers to Trade Section

Guy Wilmington, Acting Manager, Technical and Regulatory Barriers to Trade Section

Therapeutic Goods Administration, Department of Health and Aged Care

Rita Maclachlan, Acting Director, Conformity Assessment Branch

Robert Tribe, Chief Good Manufacturing Practice Auditor



Appendix D - Exhibits

Proposed IPPA with India

No 1 Indian and Pakistan Nuclear Testing (provided by DFAT)

Proposed MRA with Iceland, Liechtensein and Norway

No 1 Material relating to Nulite Systems International Pty Ltd