MUTUAL RECOGNITION AGREEMENT ON CONFORMITY ASSESSMENT IN RELATION TO MEDICINES GOOD MANUFACTURING PRACTICE INSPECTION AND CERTIFICATION BETWEEN THE GOVERNMENT OF AUSTRALIA AND THE GOVERNMENT OF CANADA (CANBERRA, 16 MARCH 2005)

[2005] ATNIF 2

Documents tabled on 11 May 2005:

National Interest Analysis [2005] ATNIA 8
with attachment on consultation

Text of the Proposed Treaty Action

Regulation Impact Statement

<u>Background information:</u>

Political Brief on Canada

Country Fact Sheet

List of Other Treaties with Canada

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NATIONAL INTEREST ANALYSIS: CATEGORY 1 TREATY

SUMMARY PAGE

Mutual Recognition Agreement on Conformity Assessment in Relation to Medicines Good Manufacturing Practice Inspection and Certification between the Government of Australia and the Government of Canada (Canberra, 16 March 2005) [2005] ATNIF 2

Nature and timing of proposed treaty action

1. The Agreement was signed on 16 March 2005. It will enter into force on the first day of the second month following the date on which the Parties have exchanged notes confirming the completion of their respective procedures for the entry into force of the Agreement, pursuant to Article 17(1).

2. The exchange of notes will occur as soon as practicable after the treaty has been tabled in Parliament and JSCOT has reported on the treaty.

3. The operational phase of the Agreement shall commence on the first day of the month following the successful completion of the Confidence Building Exercise pursuant to Article 17(2).

Overview and national interest summary

4. The Agreement provides for the mutual recognition of certification and for the acceptance of Certificates of Good Manufacturing Practice (GMP) of manufacturers of medicines.

5. The Agreement will improve market access for Australian exporters by reducing or eliminating the risks, time delays and costs associated with obtaining regulatory approvals for entering products into the Canadian market. It allows each country to maintain its standards to preserve the health and safety of its people and to protect its environment.

6. The Agreement will be legally binding and reinforce existing, voluntary, Pharmaceutical Inspection Cooperation Scheme (PIC/S) for GMP inspections in relation to medicines. The PIC/S is an international cooperative arrangement which provides for the exchange of information on GMP inspections, the training of GMP inspectors, the acceptance of inspection reports and certificates and the development of guideline documents on GMP inspections.

Reasons for Australia to take the proposed treaty action

7. Total trade between Australia and Canada in regulated Medicines for human use increased from $44 million in 2000/2001 to more than $67 million in 2004. Australian imports of Medicines from Canada increased from $11 million in 2000/2001 to more than $17 million in 2004 whilst Australian exports to Canada increased from $33 million in 2000/2001 to $50 million in 2004.

8. Goods subject to mandatory technical regulations in the country of import often need to be tested and/or certified for compliance with those requirements by a body located in that country. This adds to the costs associated with exporting products to these other markets and to the costs of imported products.

9. The Therapeutic Goods Administration (TGA) of the Department of Health and Ageing considered a number of options to address the problem of time delays and costs associated with the non-acceptance of GMP conformity assessment activities between Australia and Canada. These options included retaining the current system or entering into bilateral single-sector agreement. After careful consideration, the TGA decided that a bilateral single-sector Mutual Recognition Agreement on Conformity Assessment in relation to Medicines Good Manufacturing Practice Inspection and Certification would strengthen the health regulatory cooperation and formalise the current agency level PIC/S arrangement. Furthermore, the Agreement would improve trade relationships between Australia and Canada and provide significant cost savings for Australian exporters sending Medicines to Canada.

10. The Agreement will enable conformity assessment, allowing GMP inspection and certification of Medicines intended for sale in, and manufacturing processes for Medicines intended for export to, the other Party's territory to be undertaken *in the country of export*. This will generate substantial reductions in non-tariff barriers by enabling Australian producers to have their Medicines fully assessed in Australia for conformity to Canada's GMP standards and legal requirements and hence be acceptable to the Canada regulatory authority prior to export. It is expected that there will be enhanced growth in trade if regulatory barriers to entry, such as those mentioned, can be reduced or removed.

11. At present, each batch of Australian-made Medicines exported to Canada is required to be re-analysed upon entry into Canada. The Agreement allows for a batch certificate issued by the manufacturer in Australia to accompany each batch of Medicines shipped to Canada. This batch certificate will attest that the batch meets the Canadian requirements and would eliminate the need for re-analysis at import. Australia requires the sponsor to hold a batch certificate for imported products, but TGA does not have the requirement to retest on import.

12. Additional benefits to Australia in relation to the Agreement include:

- reduction in time delays for product testing and certification substantially improving marketability of products;

- the formalisation of current agency level arrangements to a treaty status agreement that is enforceable through international law and therefore imposes a higher level of commitment on the Parties;
- Australian exporters of medicine products covered in the Agreement having a competitive advantage over foreign exporters seeking to access the Canadian market without an equivalent agreement in place with Canada; and
- economies of scale can be derived where products are assessed and conformance documentation is issued by the same regulatory authority for both the Australian and Canadian markets at the one time. These lower costs provide the potential for consumers to benefit from lower prices and a wider range of choice in domestic markets.

13. Australia has already concluded similar agreements with the European Community (EC), the European Economic Area/European Free Trade Association (EFTA) and Singapore.

Obligations

14. The basic mutual recognition agreement obligation is for both Parties to recognise that the importing party accepts GMP compliance certification to their requirements undertaken by the relevant regulatory authority in the exporting party (Article 4). Australia will recognise Canada's GMP compliance certificates of manufacturers of Medicines as acceptable forms of evidence in support of applications for entry on the Australian Register of Therapeutic Goods (ARTG) and Canada will recognise TGA's GMP compliance certificates.

15. Article 2 limits the scope of the Agreement to the respective territories of the Parties (paragraph 1 and 2), and outlines the scope of Medicines that are subject to the Agreement (paragraph 3 and 4). If one Party has a similar Agreement with a third Party, the other Party is not bound to accept the results of a GMP Inspection undertaken by the third Party unless it expressly agrees to do so (paragraph 7).

16. Article 2 also clarifies that the Mandatory GMP requirements (as specified in Appendix 3 and the Joint Sectoral Group's Maintenance Program) covered by the Agreement are the Mandatory GMP requirements of the Parties (paragraph 6).

17. Article 3 provides for the exchange of information between the two Parties. Any significant changes to the Mandatory GMP requirements and GMP Compliance Program are to be notified to the other Party within at least 60 calendar days, unless health, safety or environmental protection concerns warrant more urgent action (paragraph 2).

18. Article 5 allows for the Inspection Service of the exporting Party to issue a Compliance Certificate that certifies that a manufacturer of a Medicine located in the territory of the exporting Party is regularly inspected, is appropriately authorised to Manufacture the relevant Medicines and complies with mandatory GMP requirements of either the importing or exporting Party (paragraph 1).

19. Article 5 also lays out the information to be included in a GMP Compliance Certificate and that the certificate should be issued in less than 30 calendar days unless there are exceptional circumstances when this time period can be extended to 60 calendar days (paragraph 2 and 3).

20. Article 7 establishes a Joint Sectoral Group (JSG) composed of an equal number of senior representatives from both Parties with the relevant expertise and understanding of the Agreement (paragraph 1 and 2) to be responsible for administering and facilitating the effective functioning of the Agreement. The JSG's responsibilities include developing, managing and assessing the Confidence Building Program, resolving any questions or differences relating to interpretation, operation or application of the Agreement, and developing and managing the Joint Sectoral Group's Maintenance Program (paragraph 3).

21. Article 8 provides that the Parties are not obliged to disclose confidential propriety information to the other Party unless necessary to demonstrate the competence of its Regulatory Authority to conduct GMP Inspection and GMP Compliance Program activities (Paragraph 1). The Parties must, in accordance with their applicable laws protect the confidentiality of the propriety information disclosed in connection with GMP Inspection and GMP Compliance activities (paragraph 2).

22. Article 8 also allows for each Party to reserve the right to make public the results of any GMP Inspection in situations in which public health and safety may be affected (paragraph 3) subject to the confidentiality obligations as referred to in paragraphs 1 and 2.

23. Article 9 makes it clear that each Party retains all authority under its laws to interpret and implement its own mandatory requirements (paragraph 1). The Agreement does not limit the authority of a Party to determine the level of protection it considers necessary with regard to health, safety and the environment (paragraph 2) or to take all appropriate measures whenever it ascertains that products may not conform with its Mandatory GMP Requirements (Paragraph 3). These measures can include withdrawing Medicines from the market, prohibiting their placement on the market, restricting their free movement, initiating a Medicine recall, initiating legal proceedings or otherwise preventing the recurrence of such problems, including through prohibition on imports. If a Party takes such measures, it shall notify the other Party within 15 calendar days of taking the measures, providing its reasons (paragraph 3).

24. Article 12 allows for joint GMP inspections to be conducted in order to develop common understandings and interpretation of practice and requirements (paragraph 1). The fees for such joint GMP Inspections shall be charged only by the Regulatory Authority of the Party in whose territory the inspection is carried out (paragraph 2).

25. Article 12 also allows the Regulatory Authority of a Party to conduct its own GMP Inspection of manufacturers in the other Party's territory for reasons identified to the other Party. Such GMP Inspections shall be notified in advance to the other Party, which has the option of joining the GMP Inspection. Recourse to this safeguard clause shall only be exercised in exceptional circumstances for the purpose

of health and safety and shall only occur with the consent of the manufacturer (paragraph 3).

26. Article 14 provides that the Parties shall conduct a Confidence Building Process in accordance with a confidence building program developed by the Joint Sectoral Group to determine the equivalency or otherwise of their respective Mandatory GMP requirements in relation to a particular Medicine and the equivalence and capabilities of the GMP Inspection procedures and the GMP Compliance Programs of the Regulatory Authorities (Paragraph 1). The confidence building exercise will commence upon entry in force of the Agreement and will be completed within 12 months (paragraph 2). Before the end of the Confidence Building Exercise, the JSG shall undertake a joint assessment of the equivalency and capabilities of the GMP Inspection procedures and GMP Compliance programs of the Regulatory Authorities (paragraph 4). The Confidence Building is completed once equivalency of the GMP Inspection procedures and Compliance Programs are reached, if they are not initially equivalent the Confidence Building Exercise will be extended until they are (paragraph 5 and 6). At the end of the Confidence Building Exercise, the JSG shall issue its findings with respect to equivalency of the Mandatory GMP Requirements in relation to Medicines.

27. Article 15 ensures that the JSG maintains an efficient and effective "two-way" alert system and that the contact points are specified in the JSG's maintenance program (paragraph 1). The Regulatory Party of one Party shall inform the Regulatory Party of the other Party with appropriate speed in case of quality defects, batch recalls, counterfeiting and other problems concerning quality (paragraph 2). The Parties shall also ensure that any suspension or withdrawal of a Manufacturing Authorisation which could affect the protection of public health, is communicated to each other with the appropriate degree of urgency.

28. Conformity assessment of manufacturers of medicinal products is undertaken by the inspection services identified in Appendix 2 of the Agreement.

Implementation

29. The *Therapeutic Goods Act 1989* (the Act) contains provisions enabling the acceptance of conformity assessment attestations from conformity assessment bodies in countries with which Australia has a mutual recognition agreement dealing with conformity assessment of good medicine manufacturing practice. Such an agreement is referred to in the Act as a "non EC/EFTA MRA".

30. To implement the Agreement, the Minister will have to make a declaration under section 3B of the Act to the effect that Canada is a country covered by a non EC/EFTA MRA. The declaration is required to be published in the Gazette. In addition, the Secretary will have to approve, in writing, Canadian conformity assessment bodies that can issue attestations of conformity for the purposes of the Act.

Costs

31. It is not envisaged that there will be any extra cost to the Australian Government, States and Territories or Industry under the Agreement as the Agreement reinforces an existing, voluntary PIC/S agreement. The overall benefits of a mutual recognition agreement include ensuring certainty of acceptance of certification and should result in a reduction in delays and costs associated with certification.

32. Attendance by Australian representatives at meetings of the Joint Sectoral Group established under the Agreement will mostly be incorporated with other similar work being conducted by the TGA. Additional costs will be minimal and therefore will be met from the TGA's existing budget.

Regulation Impact Statement

33. A Regulation Impact Statement is attached.

Future Treaty Action

34. Article 18(1) provides for amendment to the Agreement by mutual agreement of the Parties. The amendments shall enter into force on the date on which the Parties exchange notes confirming the completion of their respective procedures for the entry into force of the amendments, pursuant to Article 18(2).

35. Any amendments would be subject to Australia's domestic treaty process.

Withdrawal or Denunciation

36. Article 17(3) of the Agreement provides that either Party may terminate the Agreement in its entirety by giving the other Party six months' advance notice in writing. Following termination of the Agreement, a Party shall continue to accept the results of GMP Compliance Certification obtained prior to termination unless that Party decides otherwise based on health, safety and environmental protection considerations, pursuant to Article 17(4).

37. Termination of the Agreement by Australia would be subject to our domestic treaty process.

Contact details

Office of Devices, Blood and Tissues
Therapeutic Goods Administration
Department of Health and Ageing

Mutual Recognition Agreement on Conformity Assessment in Relation to Medicines Good Manufacturing Practice Inspection and Certification between the Government of Australia and the Government of Canada, Canberra, 16 March 2005
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CONSULTATION

1. State and Territory representatives were advised of the proposed Agreement through the Department of Health and Ageing's notification process to the Commonwealth – State – Territory Standing Committee on Treaties. The individual Premiers and Chief Ministers of all States and Territories were consulted in writing at the beginning of the negotiations and there was overall support for the Agreement. The Agreement will not have a great impact on the States and Territories, as the level of safety for medicinal products will not change.

2. The relevant industry associations – Medicines Australia (formerly the Australian Pharmaceutical Manufacturers Association (APMA)) for prescription medicines, and the Australian Self Medication Industry (ASMI) for non-prescription medicines were consulted and supported entering into the Agreement.

3. The Complementary Healthcare Council of Australia (CHC) raised concerns in relation to the effect of the proposed MRA in relation to complementary medicines, given that Canada was in the process of developing new GMP guidelines for natural health products (NHPs). Since CHC's concerns were raised Health Canada has introduced a new regulatory framework for natural health products with its own manufacturers' self-certification of GMP requirements for NHPs. This new regulatory framework includes vitamins, minerals, herbal remedies and homeopathic medicines. Canada does not require GMP certification for NHPs and Australia does, therefore these products have been excluded from the scope of the MRA. As Canada has indicated that NHPs will not require retesting at import, Australian manufacturers should not be disadvantaged by this exclusion.

4. The following is a list of organisations consulted during the negotiation of the Agreement:

Industry Associations
Medicines Australia (formerly the Australian Pharmaceutical Manufacturers Association) (prescription medicines)
Australian Self-Medication Industry (non-prescription medicines)
Complementary Healthcare Council of Australia

Commonwealth Agencies
Department of Foreign Affairs and Trade
Attorney General's Department
Department of Industry, Tourism and Resources

State/Territory Governments
The Premier of New South Wales
The Premier of Victoria
The Premier of Queensland
The Premier of Tasmania
The Premier of South Australia
The Premier of Western Australia
The Chief Minister of the Northern Territory
The Chief Minister of the Australian Capital Territory

CANADA: POLITICAL BRIEF

1. When Liberal Party Prime Minister Paul Martin took office in December 2003, he immediately announced sweeping changes to government and an ambitious reform agenda, focusing on social issues such as health, welfare and indigenous initiatives.

2. Prime Minister Martin called an early election in order to secure a new mandate from the Canadian people. Although the Liberal Party won its fourth consecutive term in the general elections in June 2004, it lost its majority. Minority government has meant an increased focus on the domestic agenda and the Government has had to work with all opposition parties to pass legislation. The first test for the Government was the passing of its March 2005 budget; the Conservative party announced it would not defeat the budget because it was too early for an election. While an election is possible any time it is more likely in 2006.

3. A minority government is not unprecedented in Canadian political history – it will be the ninth minority government since federation in 1867. The last minority government was in 1979. Experience has shown, however, that such governments are difficult to manage and tend to be short-lived, averaging a life-span of 16 months.

4. In October 2004, the Government outlined its priorities for the 38th Parliament, echoing plans announced earlier to improve health care, child and aboriginal care, a new deal for cities and to continue to strengthen the economy. On the environment the government pledged to respect its Kyoto commitments. In the March 2005 budget the Finance Minister announced a five year approach involving additional spending of C$42 billion, including C$12.8 billion defence spending, C$5 billion for the environment, and increased spending on child care, cities and tax relief. Earlier in September 2004, Canada's Federal and Provincial governments agreed to a ten year plan to strengthen and enhance Canada's health care system, totalling C$41 billion.

5. Mr Martin has highlighted improving relations with the United States as one of his highest priorities. Canada's predominant bilateral relationship with the US is defined by trade, history, shared geography and a mutual set of values. With more than $1.9 billion in goods and more than 300,000 people moving across the Canada-U.S. border each day, both countries have a critical stake in each other's economic security.

6. The Australia-Canada relationship is mature, highly productive and broadly based. Trade relations go back over one hundred years and formal diplomatic links are sixty years old. Historical parallels in social and cultural developments have produced similar legal regimes and institutions of government, and today both countries face comparable public policy challenges in areas such as health, transport and regional development.

CANADA

Fact Sheet

General information:

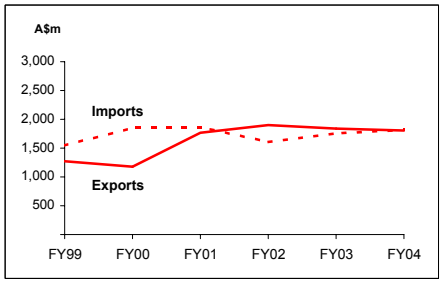
Capital: Ottawa
Surface area: 9,971 thousand sq km
Official languages: English, French
Population: 31.6 million (2003)
Exchange rate: A$1 = C$ 0.9427 (Jun 2004)

Head of State:
H.M. Queen Elizabeth II, represented by Governor-General H.E. The Rt. Hon. Adrienne Clarkson
Head of Government:
Prime Minister The Rt. Hon. Paul Martin PC

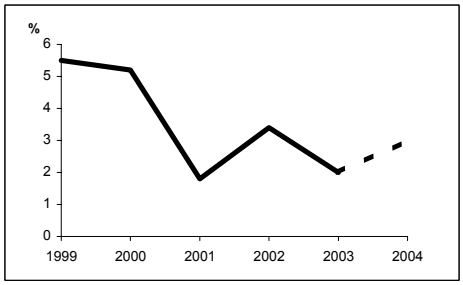
Recent economic indicators:

	1999	2000	2001	2002	2003(a)	*2004(b)*
GDP (US$bn):	661.3	724.2	715.1	736.0	866.9	*951.3*
GDP per capita (US$):	21,752	23,598	23,052	23,468	27,408	*29,803*
Real GDP growth (% change YOY):	5.5	5.2	1.8	3.4	2.0	*3.0*
Current account balance (US$m):	1,760	20,590	17,420	14,910	18,630	*23,990*
Current account balance (% GDP):	0.3	2.8	2.4	2.0	2.1	*2.5*
Goods & services exports (% GDP):	43.2	45.6	43.5	41.1	37.8	*39.0*
Inflation (% change YOY):	1.7	2.7	2.5	2.2	2.8	*2.2*
Unemployment rate (%):	7.6	6.8	7.2	7.7	7.6	*7.1*

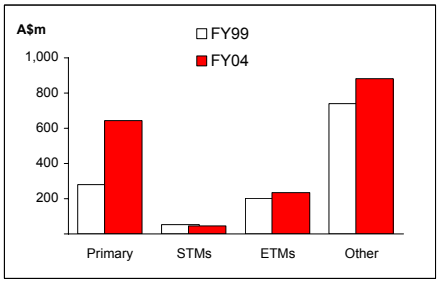
Australia's trade with Canada



Real GDP growth



Australia's exports to Canada



Australia's trade relationship with Canada:

Major Australian exports*, 2003-2004 (A$m):

Nickel ores	291
Alcoholic beverages	197
Arms & ammunition	63
Medicaments (incl. veterinary)	57
Bovine meat	43

**Includes A$812m of confidential items, 44.9% of total exports.*

Major Australian imports, 2003-2004 (A$m):

Internal combustion piston engines	217
Aircraft & parts	120
Arms & ammunition	104
Telecommunications equipment	100
Meat (excl. bovine)	95

Australian merchandise trade with Canada, 2003-2004:

		Total share:	*Rank:*	*Growth (yoy):*
Exports to Canada (A$m):	1,806	1.7%	15th	-1.7%
Imports from Canada (A$m):	1,818	1.4%	16th	3.6%
Total trade (exports + imports) (A$m):	3,624	1.5%	17th	0.9%
Merchandise trade deficit with Canada (A$m):	13			

Australia's trade in services with Canada, 2003-2004:

		Total share:
Exports of services to Canada (A$m):	453	1.3%
Imports of services from Canada (A$m):	378	1.1%
Services trade surplus with Canada (A$m):	75	

Canada's global trade relationships:

Canada's principal export destinations, 2003:

1	United States	86.4%
2	Japan	2.1%
3	United Kingdom	1.5%
4	China	1.2%
5	Germany	0.7%
13	*Australia*	*0.3%*

Canada's principal import sources, 2003:

1	United States	60.6%
2	China	5.6%
3	Japan	4.1%
4	Mexico	3.6%
5	United Kingdom	2.7%
19	*Australia*	*0.5%*

Compiled by the Market Information and Analysis Section, DFAT, using the latest data from the ABS, the IMF and various international sources.

(a) All recent data subject to revision; (b) EIU forecast.

Fact sheets are updated biannually; next update: May 2005

List of Other Treaties with Canada

- Trade Agreement with Canada (CANATA)
  [1960] ATS 5

- Agreement concerning the Application of the Canada Pension Plan to Locally Engaged Employees of the Government of Australia in Canada
  [1966] ATS 19

- Agreement with Canada many concerning Uninsured and Insured Parcels
  [1969] ATS 8

- Exchange of Letters constituting an Agreement concerning the future Operation of the Trade Agreement with Canada of 12 February 1960
  [1973] ATS 28

- Exchange of Notes constituting an Agreement with Canada concerning the Launching of a Canadian Rocket from Woomera - COSRAY 75
  [1976] ATS 22

- Convention with Canada for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income
  [1981] ATS 14

- Agreement with Canada concerning the Peaceful Use of Nuclear Energy
  [1981] ATS 8

- Exchange of Notes constituting an Agreement with Canada for Sharing Consular Services Abroad
  [1986] ATS 18

- Agreement with Canada Relating to Air Services
  [1988] ATS 12

- Treaty with Canada on Mutual Assistance in Criminal Matters
  [1990] ATS 11

- Films Co-Production Agreement with Canada
  [1990] ATS 37

- Exchange of Notes constituting an Agreement with Canada to amend and to provide for International Obligation Exchanges under the Agreement concerning the Peaceful Uses of Nuclear Energy of 9 March 1981
  [1995] ATS 19

- Exchange of Notes constituting two Agreements with Canada to provide for Certain Nuclear Transfers under the Agreement concerning the Peaceful Uses of Nuclear Energy
  [1995] ATS 19

- Agreement with Canada concerning the Protection of Defence Related Information Exchanged between Them
  [1996] ATS 16

- Protocol amending the Convention with Canada for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income
  [2002] ATS 26

- Agreement on Social Security with Canada
  [2003] ATS 4

List of Other Treaties of the same type with other countries

- Agreement on Mutual Recognition in Relation to Conformity Assessment, Certificates and Markings between Australia and the European Community (Canberra 24 June 1998)
  [1999] ATS 1999 2

- 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 [European Free Trade Association – European Economic Area], (Brussels 29 April 1999)
  [2000] ATS 17

- Mutual Recognition Agreement between Australia and the Republic of Singapore on Conformity Assessment (Canberra, 26 February 2001)
  [2001] ATS 9

- Agreement between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (Wellington, 10 December 2003)
  [2003] ATNIF 22.