AGREEMENT BETWEEN THE GOVERNMENT OF AUSTRALIA AND THE GOVERNMENT OF NEW ZEALAND FOR THE ESTABLISHMENT OF A JOINT SCHEME FOR THE REGULATION OF THERAPEUTIC PRODUCTS

DONE AT WELLINGTON ON 10 DECEMBER 2003

[2003] ATNIF 22

Documents tabled on 30 March 2004

National Interest Analysis

Text of the Proposed Treaty Action

Regulation Impact Statement

Annexes:

Consultations

New Zealand political brief

New Zealand fact sheet

List of other treaties with New Zealand

NATIONAL INTEREST ANALYSIS: CATEGORY B TREATY

SUMMARY PAGE

Agreement Between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products done at Wellington on 10 December 2003
[2003] ATNIF 22

Date of Tabling of Proposed Treaty Action

1. 30 March 2004.

Nature and Timing of Proposed Treaty Action

2. The Agreement was signed at Wellington on 10 December 2003. It will enter into force on the date on which Australia and New Zealand "the Parties" have exchanged diplomatic notes confirming the passage in each country of legislation that will give effect to the joint regulatory Scheme that the Agreement will establish (Article 23). This is proposed to occur as soon as practicable after the Australian and New Zealand requirements for parliamentary consideration of the Agreement have been met and the legislation passed. The target date for commencement of the joint regulatory scheme for therapeutic products is 1 July 2005.

Overview and National Interest Summary

3. The principal objective of the Agreement is to safeguard public health and safety by establishing and maintaining a joint scheme between Australia and New Zealand, consistent with international best practice, for the regulation of the quality, safety and efficacy or performance of therapeutic products, and of their manufacture, supply, import, export or promotion (Article 2). Therapeutic products include medical devices, prescription medicines, over-the-counter medicines and complementary medicines.

4. The Agreement provides that this scheme ("the joint Scheme") will be administered in both countries by a single regulatory Agency to be established under Australian legislation (the "Agency"), and that the joint Scheme and the Agency will be overseen by a Ministerial Council comprising the Australian and New Zealand Health Ministers. The Agency will replace the Australian Therapeutic Goods Administration and the New Zealand Medicines and Medical Devices Safety Authority.

5. The Agreement gives effect to the intention of the Trans Tasman Mutual Recognition Arrangement ("TTMRA") that Australia and New Zealand will work together to resolve the various special exemptions that operate under the Arrangement, including the special exemption for therapeutic products. The Agreement is in the national interest because it will continue the development of a more integrated trans-Tasman economy, an aim of the Australia New Zealand Closer Economic Relations Trade Agreement ("CER"), whilst delivering public health benefits for Australia by providing Australia with an enhanced and sustainable regulatory capacity for therapeutic products.

Reasons for Australia to Take the Proposed Treaty Action

6. The TTMRA, as part of the package of agreements that is the CER, aims to develop a more integrated trans-Tasman economy by removing regulatory impediments and allowing goods to be traded freely between Australia and New Zealand. In principle, under the TTMRA, a good which may legally be sold in one country should legally be able to be sold in the other. Goods need only comply with the standards or regulations for the sale of goods applying in the jurisdiction in which they are produced or through which they are imported.

7. However, certain goods, including therapeutic products, were specifically exempted from the TTMRA as it was not considered appropriate to have mutual recognition apply to them because of the significant differences between the Australian and New Zealand regulatory arrangements. The TTMRA provides that Australia and New Zealand are to undertake trans-Tasman cooperation programs to examine these regulatory differences with a view to addressing them through mutual recognition, harmonisation or permanent exemption from the TTMRA.

8. The Agreement is the result of this joint work to address the special exemption for therapeutic products. Australia and New Zealand have agreed that harmonisation, including the establishment of a joint regulatory agency is the preferred solution for this exemption. Harmonisation should reduce costs to both Australia and New Zealand firms wishing to export to the other country by reducing or eliminating differences in regulatory standards. It should also produce some administrative savings from reduced regulatory duplication in relation to licence applications, evaluation of therapeutic products, monitoring, scheduling and enforcement.

9. The complexity of therapeutic products is increasing, accompanied by a rising demand for specialist evaluators which is not matched by an equivalent expansion in specialist expertise. Harmonisation and elimination of duplication should also enhance regulatory sustainability by reducing competition with New Zealand for specialist evaluators.

10. The Agreement will deliver long term benefits to Australia by:
- reducing regulatory compliance costs for that part of the Australian therapeutic products industry that exports to New Zealand, or wishes to export to New Zealand, by replacing the current separate regulatory controls on therapeutic products in both countries with a single set of regulatory controls (eg single applications rather than dual applications and faster turnaround times for approval to access both markets);
- leading to consideration over time of Australia and New Zealand as a 'single market' and thus to the greater trans-Tasman integration of business operations and strategies, one of the aims of CER; and
- due to the creation of a single regulatory Agency for both countries, ensuring Australia remains a regional centre of excellence for therapeutics regulation by maintaining regulatory capacity in the face of emerging technologies, and enabling Australia and New Zealand to better influence global and regional standard setting.

Obligations

11. The Parties have agreed to establish the joint Scheme to regulate the quality, safety, efficacy and performance of therapeutic products, and in particular for the regulation of the manufacture, supply, import, export and promotion of therapeutic products (Article 3). The joint Scheme will involve standard setting in this area; licensing; post-market monitoring; and

enforcement of regulatory requirements. The existing therapeutic product regulatory systems of both countries will be integrated under the joint Scheme.

12. Australia has agreed to establish, as a body corporate under Australian legislation, the Agency that will administer the joint Scheme in both countries (Article 5). The Treaty establishes the Board that will govern the Agency (Article 6). The Agency's functions will include pre-market evaluation and assessment, setting standards for the manufacture, supply, import, export or promotion of therapeutic products, determining applications for approvals for such activities, and post-market monitoring and surveillance to ensure compliance with the joint Scheme. Regulatory decisions of the Agency, such as decisions regarding applications for 'Approvals' in relation to the manufacture or supply of therapeutic products, will have effect in both countries, unless otherwise specified by the Agency (Article 11).

13. Australia has agreed to only introduce into Parliament that part of the Australian legislation that establishes the Agency with the agreement of New Zealand (Article 3(8)). This ensures New Zealand has some control over the way the Agency is established, given that the Agency will regulate therapeutic products in New Zealand as well as Australia, and its decisions will have effect under New Zealand law. Under this arrangement both Governments will be assured that the Agency is established according to the method agreed under the Agreement. This arrangement also applies to any Government amendments to the establishment provisions.

14. The joint Scheme and the Agency will be overseen by a Ministerial Council comprising of the Australian and New Zealand Health Ministers (Article 4). This Ministerial Council will appoint the Board of the Agency, which will be responsible to the Ministerial Council for the governance of the Agency. The Ministerial Council will also make common Rules that will contain many of the regulatory requirements of the Scheme (Article 9). The more technical requirements (eg product quality and safety standards) will be in common Orders to be made by the Managing Director of the Agency. (Articles 7(2) and 10).

15. Australia and New Zealand are both required to legislate to give effect to the process outlined in the Agreement for the Parliamentary scrutiny of these common Rules and Orders (Articles 9 and 10). The Parties have agreed that they are to be tabled in, and disallowable by, both Parliaments. They have also agreed that if Rules or Orders are disallowed by either Parliament, they will have no effect in either country. This is to ensure that the Agency can administer the same set of regulatory arrangements in both countries.

16. The Parties have agreed to a set of principles concerning the accountability of the Agency (Article 8). That is, the Agency will be accountable to the Parties for the performance of its functions; the appropriate level of accountability is that which would normally apply to a regulatory agency established by the legislation of each Party; and the Parties agree to minimise duplication in accountability requirements. Within this set of Principles, it is open to the Parties to apply statutory accountability regimes that apply to similar regulatory agencies, to the Agency. The Parties are required to consult one another in relation to accountability regimes. The Parties have also agreed to certain specified accountability requirements, that is, the provision of annual reports, financial statements and joint auditing of financial statements.

17. Each Party has agreed to legislate to provide for the merits review of regulatory decisions of the Agency by an independent review tribunal. Decisions of the Agency will have effect, subject to orders made by the review tribunal in either jurisdiction. The

Government proposes that the merits review tribunal for Australia will be the Administrative Appeals Tribunal. New Zealand will provide a new tribunal to consider applications for review lodged in New Zealand. Members of the tribunals of both countries will be drawn from a central panel that will have the expertise needed to review a particular decision. Under this arrangement the AAT will continue to review decisions equivalent to those it can currently review under the *Therapeutic Goods Act 1989*.

18. There is provision in the Agreement for either Party to decide that particular products should not be regulated under the Scheme (Article 12). However, the Agreement provides that this may only occur if the Party considers that this is necessary because of exceptional circumstances, and that the proposed action will not compromise public health or safety in its territory. Any departures must be kept under review.

19. The Parties agree to provide the initial funding for the Agency and to transfer assets from the pre-existing regulatory bodies (Article 15).

20. The Parties will conduct and conclude a review of the effectiveness of the Scheme and the Agency, no later than 5 years after the date of entry into force of the Agreement, with a view to making any necessary improvements (Article 17).

Implementation

21. The joint Scheme will be implemented through primary legislation in both countries and Rules and Orders. It is proposed to release an exposure draft of the proposed Australian Bill for public consultation before it is introduced into Parliament, together with an explanatory document providing detail of the remainder of the proposed regulatory Scheme.

22. It is anticipated that the Australian Bill will provide for:
- the establishment and corporate personality of the Agency;
- the Rules and Orders to have the force of law in Australia;
- Parliamentary scrutiny of the Rules and Orders (disallowance);
- administrative and judicial review of Agency decisions;
- Agency functions and powers; and
- securing compliance (eg offences, penalties, powers of Agency officials).

23. Rules made by the Ministerial Council will provide for the matters set out in Article 9 of the Agreement. Examples of these matters are:
- pre-market application procedures for the major product groups to be regulated – prescription medicines, over-the-counter medicines, complementary medicines, medical devices and other therapeutic products including some sunscreens and blood and blood components;
- providing for authoritative standards to apply in relation to therapeutic products;
- other aspects of the regulatory process for therapeutic products, such as good manufacturing practice (GMP) requirements, product licences, scheduling, advertising, import and export requirements, and fees and charges;
- the terms and conditions of appointment of members of the Agency Board, members of the expert committees to be established to advise the Managing Director of the Agency, and members of the Merits Review Panel.

24. The target date for commencement of the joint Scheme is 1 July 2005. The proposed sequence of events to implement the Agreement is as follows:

- interim Ministerial Council established ahead of entry into force of the Agreement to facilitate the making of Ministerial Council decisions regarding establishment issues (eg corporate and financial planning, location of offices and functions, infrastructure development, appointments to the agency Board and expert advisory committees) and matters relating to the regulatory scheme (eg proposed Rules);

- passage of implementing legislation and public availability of key draft Rules and draft Orders proposed to be put to the Managing Director once appointed;

- entry into force of the Agreement by exchange of notes, thus establishing the Ministerial Council and the Board and enabling the Ministerial Council to appoint the members of the Board (including the Managing Director of the Agency) and expert advisory committees;

- commencement of provisions in the Australian Implementing Legislation that enable the Agency to come into existence;

- Rules to be made by the Ministerial Council and Orders to be made by the Managing Director;

- Rules and Orders to be tabled in and scrutinised by both Parliaments; and

- commencement of joint Scheme by commencement of New Zealand Implementing Legislation, the remainder of the Australian Implementing Legislation, and those Rules and Orders that must commence at the same time.

Costs

25. Funding of the joint Scheme is discussed in detail at page 25 of the Regulation Impact Statement. In summary, the Agency will operate on a full cost recovery basis for all activities within the scope of the joint Scheme. Funding has been provided by the Australian Government for the establishment and implementation of the joint Scheme, much of which is to be recovered from industry over five years, commencing from when the joint Scheme begins to operate.

26. New Zealand has matched Australia's contribution to the infrastructure needs of the new Agency and will contribute towards a reserve fund to meet the working capital needs of the new Agency.

27. The impact on industry of the changes to cost recovery will be addressed through a Cost Recovery Impact Statement prior to determining the final level and structure of fees and charges.

Consultation

28. States and Territories have been consulted through the Standing Committee on Treaties (SCOT). Particular issues raised with them were:

- the capacity for the Agency instead of State and Territory authorities to regulate sole traders (individuals who trade in therapeutic products only within a State or Territory) under the joint Scheme; and
- the need for an exemption from the operation of the TTMRA for departures from the joint Scheme.

No significant concern was raised by States and Territories regarding these issues.

29. The main concern raised by States and Territories was the future of their role in the regulation of access to, or the availability of, scheduled drugs and poisons. They were assured that the Agreement would not be used to vary their existing roles and responsibilities in these areas. Consultation will continue with States and Territories through the exposure draft of the legislation.

30. Australian and New Zealand officials developing the joint Scheme and related Agreement also consulted widely with other Australian and New Zealand stakeholders such as representatives from the medicines and medical device industries, healthcare professional associations, consumers and key government agencies. Two discussion papers were released, one to a targeted group of stakeholders and the other to the public in both countries. Full details of the consultation on the Scheme and the Agreement are set out in Annex 1 (consultation) and the RIS at Annex 2.

Regulation Impact Statement

31. A Regulation Impact Statement is attached.

Future Treaty Action

32. Either Party may request consultations with the other Party regarding amendments to the Agreement (Article 18). Amendments enter into force when confirmed by an exchange of notes. Any amendments would be subject to the Australian treaty process.

Withdrawal or Denunciation

33. Article 20 of the Agreement provides that either Party may at any time give notice in writing though diplomatic channels to the other party of its decision to terminate the Agreement. Termination would take effect on a date agreed by the Parties or if there is no agreement, on the later of the following dates: the date, if any, specified in the notice as the date on which termination is to be effective, or three years after the date on which the notice was received. The Parties may agree that the Agreement shall terminate on different dates in respect of different therapeutic products.

34. Termination under Article 20(1) would be unilateral. It would therefore not be subject to the Australian Treaty process.

Contact details

Trans Tasman Group
Therapeutic Goods Administration
Department of Health and Ageing

DEPARTMENT OF FOREIGN AFFAIRS AND TRADE
CANBERRA

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)

Not yet in force
[2003] ATNIF 22

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

The Government of Australia and the Government of New Zealand (referred to in this Agreement as "the Parties"):

CONSCIOUS of their geographic proximity, long-standing friendship, and close historic, political, and economic relationship;

RECOGNISING the development of that relationship through the Australia New Zealand Closer Economic Relations Trade Agreement done at Canberra on 28 March 1983, and subsequent arrangements and agreements developed within that framework;

NOTING in particular the Arrangement relating to Trans-Tasman Mutual Recognition signed by the Australian Prime Minister, Premiers and Chief Ministers on 14 June 1996 and by the New Zealand Prime Minister on 9 July 1996, and the cooperation programme in relation to regulatory requirements for therapeutic products pursued under the auspices of that Arrangement;

AWARE that this relationship will be significantly strengthened and that both countries will benefit through the development of a joint Trans-Tasman scheme for the regulation of therapeutic products;

ACKNOWLEDGING their commitment to securing trade liberalisation and an outward-looking approach to trade;

CONSCIOUS of their obligations under the Agreement establishing the World Trade Organization done at Marrakesh on 15 April 1994;

AFFIRMING their shared commitment to safeguarding public health and safety through a regulatory regime consistent with international best practice for the regulation of the quality, safety, and efficacy or performance of therapeutic products; and

DESIRING therefore to establish a joint scheme for the regulation of therapeutic products in both Australia and New Zealand, to be administered by a single world-class agency responsible to both Parties;

HAVE agreed as follows:

ARTICLE 1

Definitions

For the purposes of this Agreement, unless the context otherwise requires:

Agency means the agency to be established in accordance with Article 5;

Approval means an approval or other authorisation (however described) granted by the Agency under Article 11;

Australian Implementing Legislation means the Acts of the Parliament of Australia, and any regulations made under them, that give effect to the Scheme;

Australian Minister means the Minister of the Government of Australia who is responsible for the health portfolio or any other Minister acting for or on behalf of such Minister;

Board means the board established under Article 6;

commencement date means the date on which the Scheme comes into force;

Managing Director means the managing director of the Agency appointed under Article 6, and includes an acting managing director;

manufacture, in relation to therapeutic products, means:

(a) to produce the products; or

(b) to engage in any part of the process of producing the products or of bringing the products to their final state, including engaging in the processing, assembling, packaging, labelling, storage, sterilising, testing or releasing for supply of the products or of any component or ingredient of the products as part of that process;

merits review means a review of certain decisions taken by the Agency, as provided for in Article 13;

Merits Review Panel means the panel referred to in Article 13;

Ministerial Council means the council established under Article 4;

New Zealand Implementing Legislation means the Acts of the Parliament of New Zealand, and any regulations made under them, that give effect to the Scheme;

New Zealand Minister means the Minister of the Government of New Zealand who is responsible for the health portfolio or any other Minister acting for or on behalf of such Minister;

Order means an order made by the Agency under Article 10;

Principal Member means a person designated as a Principal Member of a Review Tribunal under Article 13;

promotion includes advertising;

regulatory function means:

(a) a function of the Agency referred to in any of subparagraphs (a) to (e) of paragraph 2 of Article 5, and any function incidental to those functions;

(b) any other function of the Agency that the Rules declare to be a regulatory function; and

(c) a power exercised in the course of performing a function referred to in paragraphs (a) or (b) of this definition; and a reference to the performance of a regulatory function includes a reference to the exercise of such a power;

Review Tribunal means a Trans-Tasman merits review tribunal provided for under Article 13;

Rule means a rule made by the Ministerial Council under Article 9;

Scheme means the joint scheme described in paragraph 1 of Article 3;

supply, in relation to therapeutic products, includes:

(a) supply by way of sale, exchange, gift, lease, loan, hire or hire purchase;

(b) supply, whether free of charge or otherwise, by way of sample or promotion;

(c) supply, whether free of charge or otherwise, in the course of testing for safety, efficacy or performance, of therapeutic products in a human; and

(d) supply by way of administration to, or application in the treatment of, a human;

territory means:

(a) in relation to Australia, the territory of Australia including the territory of Christmas Island and the territory of the Cocos (Keeling) Islands, but does not include any other external territory of Australia, unless the Parties have exchanged notes agreeing the terms on which this Agreement shall so apply; and

(b) in relation to New Zealand, the territory of New Zealand, but does not include Tokelau;

therapeutic product:

(a) means:
  (i) a product that is represented in any way to be, or that is, whether because of the way in which the product is presented or for any other reason, likely to be taken to be for therapeutic use;

(ii) an ingredient or component in the manufacture of a product referred to in subsubparagraph (i);
(iii) a container or part of a container for a product, ingredient or component referred to in subsubparagraphs (i) or (ii); or
(iv) a product falling within a class of products the sole or principal use of which is, or ordinarily is, a therapeutic use; and

(b) includes:
(i) a product which the Rules provide shall be treated as a therapeutic product for the purposes of this Agreement; and
(ii) a product which is declared to be a therapeutic product in an Order made under paragraph 2 of Article 10; but

(c) does not include:
(i) a product which the Rules provide shall not be treated as a therapeutic product for the purposes of this Agreement; or
(ii) a product which is declared not to be a therapeutic product in an Order made under paragraph 2 of Article 10.

therapeutic use:

(a) means use in or in connection with:
(i) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in humans;
(ii) influencing, inhibiting or modifying a physiological process in humans;
(iii) testing the susceptibility of humans to a disease or ailment;
(iv) influencing, controlling or preventing conception in humans;
(v) testing for pregnancy in humans; or
(vi) the replacement or modification of parts of the anatomy in humans; and

(b) includes any other use which the Rules provide shall be treated as a therapeutic use for the purposes of this Agreement; but

(c) does not include any use which the Rules provide shall not be treated as a therapeutic use for the purposes of this Agreement.

ARTICLE 2

Objectives of this Agreement

1. The primary objective of the Parties in concluding this Agreement is to safeguard public health and safety in Australia and New Zealand by establishing and maintaining a joint scheme consistent with international best practice for the regulation of the quality, safety, and efficacy or performance of therapeutic products, and of their manufacture, supply, import, export and promotion.

2. The other objectives of the Parties in concluding this Agreement are:

(a) to establish a world-class regulatory agency to be responsible for the effective and efficient administration of the Scheme and to be accountable to both Parties;

(b) to establish a Ministerial Council to oversee the implementation of the Scheme and the operation of the Agency and to perform certain functions to give effect to the Scheme; and

(c) to avoid barriers to trade except where such barriers are necessary to safeguard public health or safety, or to fulfil other legitimate objectives consistent with the Parties' international obligations.

ARTICLE 3

The Scheme

1. The Parties shall adopt a joint scheme for the regulation of the quality, safety, and efficacy or performance of therapeutic products, and in particular for:

   (a) the regulation of the manufacture, supply, import, export and promotion of therapeutic products;

   (b) the setting of standards in relation to the quality, safety, and efficacy or performance of therapeutic products and their manufacture, supply, import, export and promotion;

   (c) the post-market monitoring of therapeutic products; and

   (d) the enforcement of the Scheme's requirements.

2. Where a Rule requires an Approval in relation to the manufacture, supply, import, export or promotion of a therapeutic product, each Party shall prohibit the manufacture, supply, import, export or promotion of the therapeutic product otherwise than under and in accordance with the required Approval.

3. Where a Rule prescribes the manner or circumstances in which a therapeutic product is not to be manufactured, supplied, imported, exported or promoted, each Party shall prohibit the manufacture, supply, import, export or promotion of the therapeutic product in that manner or those circumstances.

4. Where a Rule or Order prescribes requirements relating to the manufacture, supply, import, export or promotion of a therapeutic product, each Party shall prohibit such manufacture, supply, import, export or promotion unless it is carried out in accordance with the Rule or Order.

5. Each Party shall ensure the effective implementation, operation, maintenance and enforcement of the Scheme in accordance with the objectives of this Agreement and, subject to paragraph 4 of Article 11 and to Article 12, shall ensure that its joint nature is maintained.

6. The Parties shall conduct effective consultation together in relation to the legislation to be enacted by each Party to implement the Scheme, and in relation to any amendments to that legislation, with a view to ensuring that it is consistent with and gives effect to the objectives of this Agreement.

7. Each Party shall ensure that its legislation implementing the Scheme is not amended or repealed in a manner that is inconsistent with this Agreement, or would prejudice the joint nature of the Scheme or its effectiveness.

8. A Party shall not:

   (a) introduce Government legislation giving effect to paragraphs 4 or 5 of Article 5; or

   (b) introduce Government amendments to the legislation giving effect to paragraphs 4 or 5 of Article 5;

   without the written consent of the other Party, which may be withheld only if the other Party:

   (c) is of the view that the legislation is inconsistent with the requirements of paragraphs 4 or 5 of Article 5; and

   (d) outlines the nature of its concerns in a diplomatic note.

9. Each Party shall use its best endeavours to reach agreement with the other Party in relation to any other amendments to the legislation that gives effect to Article 5, including, where relevant, reflecting the position of the other Party in any papers for the Government of that Party.

10. The Parties shall cooperate closely in relation to mutual recognition or other arrangements with third countries that may affect the regulation of therapeutic products within their respective territories, with a view to securing outcomes consistent with the Scheme.

ARTICLE 4

The Ministerial Council

1. A Ministerial Council comprising the Australian Minister and the New Zealand Minister is hereby established.

2. The functions of the Ministerial Council are:

   (a) to oversee the Agency and the Scheme;

   (b) to ensure accountability in respect of the Agency, and in respect of the operation of the Scheme, to each of the Parties;

(c) to make, amend and revoke Rules in accordance with this Agreement to give effect to the Scheme;

(d) to appoint and remove the members of the Board, including the Managing Director;

(e) to establish expert advisory committees to advise the Managing Director on matters specified in the Rules, and to appoint and remove the members of those committees; and

(f) to appoint and remove members of the Merits Review Panel and to designate the Principal Members of the Review Tribunals.

3. All decisions of the Ministerial Council shall be made with the agreement of both members of the Council.

4. Subject to this Agreement, the Ministerial Council shall regulate its own procedure.

ARTICLE 5

The Agency

1. The Agency shall be established, and shall be responsible for the administration of the Scheme in the territory of both Parties, in accordance with this Agreement.

2. The function of the Agency shall be to administer the Scheme in the territory of both Parties, and includes:

(a) setting standards in relation to the manufacture, supply, import, export and promotion of therapeutic products;

(b) considering and determining applications for Approvals, and granting, amending, suspending and revoking Approvals;

(c) monitoring, auditing and enforcing compliance with the requirements of the Scheme;

(d) monitoring the quality, safety, and efficacy or performance of therapeutic products;

(e) making, amending and revoking Orders to give effect to the Scheme;

(f) providing information to the public in relation to therapeutic products;

(g) undertaking or commissioning research in relation to the quality, safety, and efficacy or performance of therapeutic products;

(h) advising the Ministerial Council on matters relating to the administration of the Scheme;

(i) monitoring international developments in regulatory excellence regarding therapeutic products and recommending enhancements to the Scheme to the Ministerial Council; and

(j) any function incidental to the functions referred to in subparagraphs (a) to (i).

3. The Agency may engage in activities (including performing functions and providing services) that fall outside the scope of the Scheme at the request of either Party on such terms and conditions as may be approved by the Ministerial Council in writing.

4. The Australian Implementing Legislation shall:

(a) establish the Agency as a body corporate, the members of which are the members of the Board;

(b) provide that the Agency has the functions specified in paragraph 2; and

(c) provide that the Agency may engage in activities specified in accordance with paragraph 3.

5. The Australian Implementing Legislation and the New Zealand Implementing Legislation shall confer such rights, powers and privileges on the Agency as are required to enable the Agency to perform its regulatory functions.

6. To avoid doubt, the Agency shall not have international legal personality.

ARTICLE 6

The Board

1. A Board is hereby established comprising:

(a) the Chair of the Board;

(b) the Managing Director of the Agency;

(c) a person with broad experience in relation to public health and regulatory matters in New Zealand;

(d) a person with broad experience in relation to public health and regulatory matters in Australia; and

(e) a person with broad experience in commercial matters.

2. The Ministerial Council shall appoint the members of the Board. The Chair of the Board and the Managing Director may only be appointed with the written agreement of both members of the Ministerial Council. The Ministerial Council shall seek to reach consensus on the appointment of the other members of the Board. Notwithstanding paragraph 3 of Article 4, in the event that consensus is not reached, the Ministerial Council:

(a) shall appoint the Board member referred to in subparagraph (c) of paragraph 1 on the recommendation of the New Zealand Minister;

(b) shall appoint the Board member referred to in subparagraph (d) of paragraph 1 on the recommendation of the Australian Minister; and

(c) shall appoint the Board member referred to in subparagraph (e) of paragraph 1 in the manner provided for in the Rules.

3. The appointments to the Board shall be made in accordance with the Rules.

4. The Ministerial Council may remove a member of the Board in the same manner in which that member may be appointed, in accordance with the Rules.

5. Subject to paragraph 6, the Board shall be responsible to the Ministerial Council for the governance of the Agency, and in particular for:

(a) financial matters concerning the Agency;

(b) the administration of the Agency;

(c) the efficiency and effectiveness with which the Agency performs its functions;

(d) the strategic direction of the Agency; and

(e) reporting to the Ministerial Council regarding the matters referred to in subparagraphs (a) to (d).

6. The Board shall not be responsible to the Ministerial Council for decisions made by the Managing Director in the performance of the Agency's regulatory functions.

ARTICLE 7

The Managing Director

1. The Managing Director shall be the chief executive of the Agency, and as such shall be responsible to the Board for the management of the Agency. The Managing Director shall manage the Agency under the direction of the Board in relation to the matters for which the Board is responsible under paragraph 5 of Article 6.

2. The regulatory functions of the Agency shall be performed by the Managing Director on behalf of and in the name of the Agency.

3. The Managing Director shall not be responsible to the Board for decisions made by the Managing Director in the performance of the Agency's regulatory functions, and in

particular the Board may not give the Managing Director a direction in relation to a particular decision required to perform a regulatory function.

ARTICLE 8

Accountability of the Agency

1. The Parties agree to the following principles:

   (a) the Agency shall be accountable to the Parties for the performance of its functions;

   (b) the appropriate level and type of accountability for the Agency is that which would normally apply to a regulatory agency established by the legislation of each Party; and

   (c) there shall be no unnecessary duplication in accountability requirements that apply to the Agency.

2. Accountability requirements that apply to the Agency may be set out in Rules, or in the Parties' domestic legislation that is applied to the Agency, or in both Rules and the Parties' domestic legislation that is applied to the Agency.

3. The Board shall, in respect of each financial year, provide to the Ministerial Council an annual report on the activities of the Agency and financial statements for the Agency, prepared in accordance with the Rules.

4. The Agency shall prepare and provide to the Ministerial Council planning documents, reports and information as specified in the Rules.

5. The financial statements of the Agency shall be audited. The Auditor-General of Australia and the Auditor-General of New Zealand shall be appointed as the joint auditors of the Agency with responsibility for the audit of the financial statements of the Agency.

6. Each Party may provide for the application to the Agency of statutory accountability regimes that apply in the territory of that Party to similar regulatory agencies to the extent and in a manner that is consistent with this Agreement, and in particular with the principles in paragraph 1. The Parties shall consult each other in relation to the application of statutory accountability regimes to the Agency, and in relation to such modifications of those regimes as may be appropriate.

ARTICLE 9

Ministerial Council Rules

1. The Ministerial Council may make Rules for the following purposes:

   (a) providing for the governance and accountability of the Agency;

(b) without limiting subparagraph (a), providing for financial matters concerning the Agency, including (without limitation) borrowing and other raising of finance by the Agency;

(c) providing for aspects of the employment arrangements for the Agency;

(d) prescribing standards of good regulatory practice to be complied with by the Agency;

(e) providing for the fees and charges that may be levied by the Agency in connection with the performance of its functions, and the payment of such fees and charges;

(f) prescribing principles or requirements to be complied with in setting fees and charges;

(g) providing for:

(i) the delegation by the Managing Director of any of the Managing Director's functions or powers, including regulatory functions that the Managing Director exercises on behalf of and in the name of the Agency;

(ii) the subdelegation of those functions or powers; and

(iii) the effect of the delegation or subdelegation;

(h) prescribing the procedure to be followed in connection with the making, amending or revoking of Orders;

(i) providing for internal review of specified decisions of the Agency in connection with the grant, amendment, suspension or revocation of Approvals, and any other specified classes of decisions of the Agency;

(j) prescribing, for the purposes of subparagraph (c) of paragraph 1 of Article 13, further classes of decision of the Agency that are subject to merits review;

(k) prescribing the procedure to be followed in connection with the appointment and removal of Board members, except in so far as it is provided for in this Agreement;

(l) prescribing the terms and conditions on which Board members hold office, including their term of office and remuneration;

(m) providing for acting appointments to the Board;

(n) prescribing Board procedure;

(o) providing for:

(i) the delegation by the Board of any of the Board's functions or powers;

(ii) the subdelegation of those functions or powers; and

(iii) the effect of the delegation or subdelegation;

(p) providing that certain products or classes of products are or are not to be treated as therapeutic products for the purposes of this Agreement;

(q) providing that certain uses of products are or are not to be treated as a therapeutic use for the purposes of this Agreement;

(r) providing for a framework for the classification of therapeutic products to enable a system or systems of access controls for therapeutic products to be applied in the territory of each Party;

(s) prescribing the circumstances in which a therapeutic product is not to be manufactured, supplied, imported, exported or promoted;

(t) prescribing the circumstances in which an Approval is required under the Scheme, whether by reference to an activity, the person engaging in the activity, the therapeutic product involved in the activity or otherwise;

(u) prescribing requirements to be complied with in relation to the manufacture, supply, import, export or promotion of therapeutic products;

(v) prescribing requirements that must be satisfied before an Approval is granted by the Agency;

(w) prescribing the procedure to be followed in connection with applications for Approvals and the determination of such applications;

(x) prescribing terms and conditions on which any class or classes of Approval may or shall be granted by the Agency;

(y) prescribing the circumstances in which Approvals may be amended, suspended or revoked and prescribing the procedure to be followed in connection with such matters;

(z) providing for regulatory approvals in respect of specified therapeutic products or classes of therapeutic products granted by regulators in specified countries to be recognised by the Agency as establishing that those products meet appropriate standards of quality, safety, and efficacy or performance, and providing for simplified procedures for applying for an Approval in respect of such products;

(aa) providing for authoritative standards or principles such as those provided in the British Pharmacopoeia, the European Pharmacopoeia, or other relevant authoritative standards or principles (as in force or existing from time to time) to apply in relation to all therapeutic products, specified therapeutic products or specified classes of therapeutic products, in circumstances where no other applicable standard or principle is prescribed by Rules or Orders;

(bb) prescribing requirements in relation to the promotion of therapeutic products;

(cc) prescribing the kinds of representations that are not to be made in relation to therapeutic products;

(dd) prescribing requirements for providing information to the Agency regarding therapeutic products and their manufacture, supply, import, export or promotion;

(ee) prescribing requirements for providing information to the public or specified classes of persons regarding therapeutic products and their manufacture, supply, import, export or promotion;

(ff) prescribing record-keeping and notification requirements in respect of the manufacture, supply, import, export or promotion of therapeutic products;

(gg) identifying matters that may be dealt with by way of Orders rather than by Rules;

(hh) setting out rules of interpretation for Rules and Orders (including rules dealing with the effect of the amendment, revocation and disallowance of Rules and Orders);

(ii) prescribing a method by which Rules or Orders shall be published for the purposes of paragraph 6 of this Article or paragraph 6 of Article 10;

(jj) providing, in accordance with Article 21, for the transition from the separate regimes operated by the Parties before the commencement date to the Scheme established by this Agreement;

(kk) providing for the establishment, terms of reference, composition and operation of expert advisory committees, and for the terms and conditions that apply to membership of such committees, including the term of office and remuneration of members;

(ll) providing for the appointment and removal of members of the Merits Review Panel and for the terms and conditions that apply to such appointments;

(mm) prescribing the procedure to be followed in connection with an application for merits review, and in conducting a merits review, in accordance with Article 13;

(nn) providing for an Approval to be given that applies in the territory of one Party only, or that applies differently in the territory of each Party, for the purposes of subparagraph (c) of paragraph 4 of Article 11;

(oo) providing for the retention of materials and documents provided in relation to applications for Approvals that are made to the Agency;

(pp) declaring that a function of the Agency is a regulatory function; and

(qq) providing for any other matters that are necessary or convenient to be dealt with under Rules in order to give effect to the objectives of this Agreement.

2. In exercising its powers to make, amend or revoke Rules, the Ministerial Council shall give effect to the objectives of this Agreement.

3. Rules may be amended or revoked by the Ministerial Council in the same manner in which Rules may be made.

4. Each Party shall legislate to provide for Rules to be tabled in the Parliament of that Party and to be subject to disallowance in whole (and not in part) by that Parliament within a reasonable time from tabling. If any Rules are disallowed by the Parliament of one Party, they shall cease to have effect for the purposes of this Agreement and the Australian Implementing Legislation and the New Zealand Implementing Legislation.

5. A Rule shall have effect under this Agreement and the Australian Implementing Legislation and the New Zealand Implementing Legislation on the later of the following dates:

   (a) any date specified in the Rule as the date on which the Rule is to have effect;

   (b) the date on which the requirements of paragraph 7 have been satisfied.

6. The Agency shall ensure that Rules are published, as soon as practicable after they are made, on the Internet or by such other method as may be specified in Rules.

7. Rules must be published, or the making of the Rules must be notified, as soon as practicable after they are made:

   (a) in the official Gazette of New Zealand, or in such other manner as may be specified for this purpose in the New Zealand Implementing Legislation; and

   (b) in the official Gazette of the Commonwealth of Australia, or in such other manner as may be specified for this purpose in the Australian Implementing Legislation.

ARTICLE 10

Therapeutic Product Orders

1. The Agency may make the following Orders:

   (a) Orders dealing with matters identified in Rules made under subparagraph (gg) of paragraph 1 of Article 9;

   (b) Orders made in accordance with the provisions of any other Rule made under paragraph 1 of Article 9.

2. Where the Managing Director is satisfied that particular products or classes of products:

   (a) are or are not therapeutic products within the meaning of this Agreement; or

(b) when used, promoted or presented in a particular way, are or are not therapeutic products within the meaning of this Agreement;

the Agency may make an Order declaring that the products, or the products when used, promoted or presented in that way, are or are not, for the purposes of this Agreement, therapeutic products.

3. Orders may be amended or revoked by the Agency in the same manner in which Orders may be made.

4. Each Party shall legislate to provide for Orders to be tabled in the Parliament of that Party and to be subject to disallowance in whole (and not in part) by that Parliament within a reasonable time from tabling. If any Orders are disallowed by the Parliament of one Party, they shall cease to have effect for the purposes of this Agreement and the Australian Implementing Legislation and the New Zealand Implementing Legislation.

5. An Order shall have effect under this Agreement and the Australian Implementing Legislation and the New Zealand Implementing Legislation on the later of the following dates:

(a) any date specified in the Orders as the date on which the Order is to have effect;

(b) the date on which the requirements of paragraph 7 have been satisfied.

6. The Agency shall ensure that Orders are published, as soon as practicable after they are made, on the Internet or by such other method as may be specified in Rules.

7. Orders must be published, or the making of the Orders must be notified, as soon as practicable after they are made:

(a) in the official Gazette of New Zealand, or in such other manner as may be specified for this purpose in the New Zealand Implementing Legislation; and

(b) in the official Gazette of the Commonwealth of Australia, or in such other manner as may be specified for this purpose in the Australian Implementing Legislation.

ARTICLE 11

Approvals

1. Any person may apply to the Agency for an Approval in relation to the manufacture, supply, import, export or promotion of a therapeutic product in accordance with the Rules. The Agency shall consider and determine the application in accordance with the Rules.

2. The Agency may grant, amend, suspend or revoke an Approval in accordance with the Rules.

3. An Approval shall apply in the territory of both Parties, and shall be given effect under the Australian Implementing Legislation and the New Zealand Implementing Legislation, unless the Approval expressly provides that it applies only in the territory of one Party, or expressly provides for differences in its application in the territories of the Parties (in this Article referred to as a **regulatory difference**).

4. An Approval may provide that it applies in the territory of one Party only, or provide for differences in its application in the territories of the Parties, where:

   (a) the Approval relates to a therapeutic product or a class of therapeutic products in respect of which a Party has notified a departure under Article 12, and the terms of the Approval give effect to that departure;

   (b) the Agency considers that it is desirable for the therapeutic product to be supplied in a different manner or subject to different requirements in the territory of the two Parties, having regard to differences in public health, safety, environmental or cultural circumstances of the Parties; or

   (c) the Rules provide for such differences.

5. The Ministerial Council shall, at least once a year, review Approvals that are subject to a regulatory difference, and consider whether there is a continuing need for each regulatory difference.

6. The Agency shall, at least once a year, review Approvals that are subject to a regulatory difference under subparagraph (b) of paragraph 4, and consider whether there is a continuing need for each regulatory difference.

ARTICLE 12

Departures from the Scheme by one Party in Exceptional Circumstances

1. Either Party may, by regulations made under that Party's Implementing Legislation:

   (a) specify a therapeutic product, or class of therapeutic products, to which this Article applies; and

   (b) exclude or modify the application of the Scheme in respect of that therapeutic product or class of therapeutic products.

2. A Party may make regulations in accordance with this Article only if satisfied that

   (a) it is necessary for it to do so having regard to exceptional public health, safety, third country trade, environmental or cultural factors that affect that Party; and

   (b) the proposed action will not compromise public health or safety in the territory of that Party.

3. Where a Party takes action under paragraph 1:

(a) The Scheme shall apply in the territory of that Party subject to the regulations made under paragraph 1;

(b) Nothing in this Agreement prevents the other Party from taking measures to prevent the importation of any therapeutic product or class of therapeutic products to which that action relates, if that therapeutic product or class of therapeutic products does not meet the requirements of the Scheme.

4. Before taking action under paragraph 1, a Party shall notify the other Party of the proposed departure from the Scheme and of the reasons for that departure, and shall afford the other Party a reasonable opportunity to comment on the proposed departure.

5. Where a Party has taken action under paragraph 1, that Party:

(a) shall keep the matter under review with a view to determining whether the exceptional factors that affect that Party continue to apply; and

(b) shall, at the request of the other Party, enter into consultations to discuss the continuing need for that departure.

6. The Ministerial Council shall, at least once a year, consider any departures in force under paragraph 1, and may make recommendations to the Parties in relation to those departures.

7. Action taken under this Article shall not be more trade restrictive than is necessary to take account of the factors referred to in paragraph 2, and shall not result in therapeutic products imported from the other Party being accorded treatment less favourable than that accorded to:

(a) such products originating in the territory of the Party which implemented the departure; or

(b) such products originating in any other country.

8. A Party that has taken action under this Article may consult with the Agency in relation to any alternative regulatory measures to be adopted pursuant to the departure, and the Agency shall if so consulted assist with the development and implementation of such measures on terms (including terms relating to the funding of the Agency's work) determined by the Ministerial Council.

9. In the context of the review provided for in Article 17, the Parties shall specifically review the operation of this Article, taking into account experience gained since the inception of the Scheme.

ARTICLE 13

Merits Review of the Agency's Regulatory Decisions

1. Each Party shall legislate to provide for the review before a Review Tribunal, in accordance with this Article, of decisions made by the Agency in relation to:

   (a) an application for an Approval;

   (b) the amendment, suspension or revocation of an Approval; or

   (c) any other matter specified in the Rules.

2. In determining a merits review, a Review Tribunal shall reconsider the matter decided by the Agency, and may exercise all the powers and discretions conferred on the Agency under this Agreement and the Rules. Each Party shall provide a Review Tribunal with the functions and powers that are necessary to conduct reviews of decisions of the Agency.

3. The Parties shall provide that a Review Tribunal may:

   (a) affirm the decision under review;

   (b) vary the decision under review; or

   (c) set aside the decision under review and:

      (i) make a decision in substitution for the decision so set aside; or
      (ii) remit the matter for reconsideration by the Agency in accordance with any directions or recommendations of the Review Tribunal.

4. The members of a Review Tribunal shall be drawn from the Merits Review Panel.

5. The Ministerial Council may from time to time appoint persons as members of the Merits Review Panel in accordance with the Rules. The Ministerial Council shall only appoint a person to the Merits Review Panel if it is satisfied the person is appropriately qualified to serve as a member of a Review Tribunal, having regard to that person's knowledge of and experience in medicine, therapeutic products, public administration or law. The term of each appointment shall be specified by the Ministerial Council.

6. The Ministerial Council shall designate:

   (a) one member of the Merits Review Panel as the Principal Member in respect of merits reviews conducted in Australia;

   (b) one member of the Merits Review Panel as the Principal Member in respect of merits reviews conducted in New Zealand.

7. Without limiting paragraphs 5 and 6, the Ministerial Council may from time to time:

(a) appoint as a member of the Merits Review Panel the holder from time to time of an office established by either Party; and

(b) designate as the Principal Member of a Review Tribunal the holder from time to time of an office established by either Party.

8. The composition of a Review Tribunal to consider and determine a merits review shall be decided by the relevant Principal Member, having regard to the expertise required for the purposes of that merits review.

9. Each Party shall provide for the transfer of merits review proceedings between jurisdictions where a Review Tribunal considers that it is in the interests of justice to do so.

10. Each Party may legislate to provide for a right of appeal to a superior court on questions of law in respect of a determination by a Review Tribunal of a merits review conducted in the territory of that Party.

11. The Parties shall consult together in relation to the procedure to be followed in connection with applying for merits review and conducting merits reviews, to ensure the effective, just and efficient determination of merits reviews. These matters shall be provided for in the Australian Implementing Legislation and the New Zealand Implementing Legislation or, if and to the extent that the Parties so agree, in Rules made by the Ministerial Council for the purposes of this Article.

12. Except as otherwise provided in this Agreement, Rules or applicable legislation, a Review Tribunal may determine its own procedure.

13. A decision by the Agency in relation to matters referred to in paragraph 1 shall have effect for the purposes of this Agreement, and shall be given effect under the Australian Implementing Legislation and the New Zealand Implementing Legislation, subject to any orders made by a Review Tribunal, or by a court of either Party on appeal from a Review Tribunal, that vary, set aside, suspend, or otherwise affect that decision.

ARTICLE 14

Judicial Review of Agency Decisions and Rules

1. Each Party may legislate to provide for judicial review before the courts of that Party of decisions and Orders made by the Agency, in the same manner as if the Agency were exercising a statutory power of decision under the laws of that Party.

2. Each Party may legislate to provide for judicial review before the courts of that Party of a Rule made by the Ministerial Council, in the same manner as if the Rules were made under a statute of that Party.

3. Legislation of a Party which provides for judicial review in accordance with this Article shall provide for the court before which judicial review proceedings have been commenced to grant a stay of those proceedings, on the application of a party to those proceedings, if the court considers that, taking into account relevant factors such as the residence of the

applicant, it would be more appropriate for the proceedings to be heard and determined in the courts of the other Party, in the interests of the effective, just, and efficient determination of those proceedings.

4. A decision by the Agency, an Order or a Rule shall have effect for the purposes of this Agreement, and shall be given effect under the Australian Implementing Legislation and the New Zealand Implementing Legislation, subject to any orders, made in the course of proceedings before a court in either Party in which judicial review has been sought as provided for in this Article, that vary, suspend, set aside or otherwise affect that decision, Order or Rule.

ARTICLE 15

Funding

1. The Parties shall provide initial funding to the Agency, and transfer to the Agency certain assets employed by each of them in connection with the regulation of therapeutic products prior to the commencement of the Scheme, on such terms as may be agreed between them prior to the establishment of the Agency. The Parties shall not be required to provide any further funding to the Agency except in accordance with paragraph 4, or as may be agreed by both Parties.

2. The fees and charges that may be levied by the Agency in connection with the performance of its functions shall be prescribed in Rules. The fees and charges shall:

   (a) be designed to recover the full costs of the Agency's operations under the Scheme in an efficient and equitable manner;

   (b) provide such incentives for the timely and efficient determination of applications by the Agency as the Ministerial Council thinks fit; and

   (c) comply with such other principles or requirements as may be prescribed in the Rules.

3. Before setting fees and charges, the Ministerial Council shall:

   (a) seek recommendations from the Board in respect of those fees and charges; and

   (b) ensure stakeholder representatives are consulted where appropriate.

4. The Ministerial Council shall determine terms and conditions as to funding where the Agency is to engage in activities (including performing functions and providing services) that fall outside the scope of the Scheme in accordance with paragraph 3 of Article 5. Without limiting the generality of this provision, a Party may agree to provide funding to the Agency in connection with such activities, or the Agency may be empowered to levy fees or charges in respect of such activities.

5. The Agency shall not be subject to income tax in the territory of either Party.

ARTICLE 16

Consultations

The Parties shall, at the written request of either, promptly enter into consultations with a view to seeking an early, equitable and mutually satisfactory solution, if the Party which requested the consultations considers that:

(a) an obligation under this Agreement has not been, is not being, or may not be fulfilled; or

(b) the achievement of any of the objectives of this Agreement is being or may be frustrated.

ARTICLE 17

Review

The Parties agree to conduct and conclude, no later than five years after the date of entry into force of this Agreement, a review of the effectiveness of the Scheme and of the Agency, with a view to agreeing to and implementing any necessary improvements.

ARTICLE 18

Amendment

If either of the Parties considers that an amendment to this Agreement would be desirable, it may request consultations with the other Party to this end. Such consultations shall be entered into promptly by the Parties, unless they agree otherwise. Any agreed amendments shall enter into force when they have been confirmed by an exchange of diplomatic notes.

ARTICLE 19

Participation of Third Parties

1. The Parties may agree to the association of any other State with this Agreement.

2. The terms of such association shall be negotiated between the Parties and that other State.

ARTICLE 20

Termination

1. Either Party may at any time give notice in writing through diplomatic channels to the other Party of its decision to terminate this Agreement.

2. Upon such notice being given, the Agreement shall terminate on a date to be agreed by the Parties in writing. The Parties may agree that the Agreement shall terminate on different dates in respect of different classes of therapeutic product. In the absence of such agreement, this Agreement shall terminate on the later of:

   (a) any date specified in the notice as the date on which the termination is to be effective; or

   (b) the date 3 years after the date on which the notice was received.

3. Upon termination of this Agreement:

   (a) the Agency shall cease to be governed in accordance with this Agreement, and shall be governed in such manner as may be specified in Australian legislation;

   (b) New Zealand shall have no interest in the Agency or its assets, except as may be determined in accordance with paragraphs 4 and 5.

4. Prior to the termination of this Agreement the Parties shall use their best endeavours to reach agreement in relation to matters arising out of that termination, including:

   (a) arrangements for use by New Zealand of the intellectual property of the Agency and information held by the Agency, as at the date of termination;

   (b) assistance to be provided by the Agency in connection with new arrangements for the regulation of therapeutic products in New Zealand; and

   (c) financial arrangements in connection with the termination of this Agreement, having regard to paragraph 3 and to the financial contributions that the Parties have made in connection with the establishment and implementation of the Scheme.

5. If agreement is not reached on the matters referred to in paragraph 4, either Party may make a written request to the other Party for the difference between them to be referred to arbitration in accordance with the Annex.

ARTICLE 21

Transitional Provisions

1. Each Party shall legislate to give effect to the transitional arrangements set out in this Article.

2. On and after the commencement date, the manufacture, supply, import, export or promotion of a therapeutic product that was lawful in the territory of one Party immediately before the commencement date continues to be lawful in the territory of that Party for a specified period by virtue of the deemed grant of a transitional approval under the Scheme on the terms and conditions (if any) that applied in respect of the manufacture, supply, import, export or promotion of that therapeutic product before the commencement date, subject to any Rules that apply under paragraph 3.

3. Every transitional approval shall be subject to the relevant applicable Rules. Without limiting subparagraph (jj) of paragraph 1 of Article 9, Rules made under that subparagraph may:

   (a) apply some or all of the provisions of the superseded legislation, with or without modification, to therapeutic products or activities that are subject to a transitional approval;

   (b) apply different specified periods to different transitional approvals for therapeutic products or activities; and

   (c) provide for the temporary extension of a transitional approval, at the discretion of the Agency or as otherwise set out in Rules.

4. Each Party shall establish a transitional system (which may include the establishment, appointment or continuation of a body) for dealing with applications received under the superseded legislation but not determined by the commencement date.

5. Applications that are received under the superseded legislation but not determined by the commencement date shall be determined in accordance with the transitional system established by the Party in whose territory the application was lodged. The transitional system:

   (a) shall ensure that the application is determined on the same basis as applied to the application before the commencement date;

   (b) shall provide for the grant of transitional approvals under the Scheme for a specified period as provided for in the Rules; and

   (c) shall grant transitional approvals only in relation to the territory of the Party that operates the transitional system.

6. Each Party may provide that applicants whose applications were lodged under the superseded legislation but which are not, or are unlikely to be, determined by the commencement date may elect to have their applications determined by the Agency under the Scheme rather than under the transitional system established by the Party.

7. All post-market activities, appeals and reviews that were commenced under the superseded legislation but not completed by the commencement date shall be completed on the same basis as if the activity, appeal or review were continuing under that legislation. However, the Parties may provide that persons other than those provided for under the superseded

legislation may conduct post-market activities, appeals or reviews, as long as the Parties ensure that, to the fullest extent practicable, the substantive effect of the superseded legislation is maintained.

8. The Parties agree that, where a therapeutic product had been approved in the territory of either Party under the superseded legislation before the commencement date, the requirements for applying for and obtaining an Approval under the Scheme shall take into account, among other relevant factors, that approval and the history of use of the product.

ARTICLE 22

Compliance with Other Laws and Regulations

1. This Agreement is not intended to affect the operation of laws affecting therapeutic products in force in the territory of either Party, except to the extent that such laws are superseded by the Australian Implementing Legislation or the New Zealand Implementing Legislation. Examples of such laws that this Agreement is not intended to affect are laws relating to biosecurity, customs controls, intellectual property and consumer protection.

2. The Parties confirm that therapeutic products in their territories shall continue to be subject to such additional requirements, whether in force before or after the Scheme commences, as well as to the requirements imposed under the Scheme.

ARTICLE 23

Entry into Force

This Agreement shall enter into force on the date on which the Parties have exchanged diplomatic notes confirming the completion of their respective domestic procedures for the entry into force of this Agreement.

IN WITNESS WHEREOF the undersigned, being duly authorised by their respective Governments, have signed this Agreement.

DONE in duplicate at Wellington on this tenth day of December 2003.

Patricia Mary Worth
Parliamentary Secretary for
The Minister for Health and Ageing

FOR THE GOVERNMENT OF
AUSTRALIA

Annette King
Minister for Health

FOR THE GOVERNMENT OF
NEW ZEALAND

ANNEX – ARBITRATION MECHANISM FOLLOWING TERMINATION

Where either Party has made a written request in accordance with paragraph 5 of Article 20, and subject to any modifications that may be agreed in writing between the Parties, the arbitration shall be carried out in accordance with the procedures set out in this Annex.

1. Each Party shall within 30 days of the receipt of the written request referred to above set out in writing the matters arising out of termination where agreement has not been reached and communicate this to the other Party.

2. Taking into account the matters which are the subject of the arbitration, the Parties shall appoint an arbitral tribunal consisting of three members. Each Party shall appoint an arbitrator within 30 days of the receipt of the second communication referred to in paragraph 1 and the two arbitrators appointed shall seek to designate by common agreement the third arbitrator, who shall chair the tribunal. Each arbitrator, including the chair of the tribunal, shall have international commercial arbitration experience and shall not be a national of either of the Parties, nor have his or her usual place of residence in the territory of one of the Parties, nor be employed by either of them, nor have dealt with any matters in relation to the Scheme in any capacity.

3. If the chair of the tribunal has not been designated within 30 days of the appointment of the second arbitrator, the Secretary-General of the Permanent Court of Arbitration shall at the request of either Party appoint the chair of the arbitral tribunal within a further 30 day period.

4. If one of the Parties does not appoint an arbitrator within the time specified in paragraph 2 of this Annex, the other Party may inform the Secretary-General of the Permanent Court of Arbitration who shall appoint the chair of the arbitral tribunal within a further 30 day period and the chair shall, upon appointment, request the Party which has not appointed an arbitrator to do so within 14 days. If after such period that Party has still not appointed an arbitrator, the chair shall inform the Secretary-General of the Permanent Court of Arbitration who shall make this appointment within a further 30 day period.

5. Before any appointments to the arbitral tribunal are made by the Secretary-General of the Permanent Court of Arbitration, the Parties shall notify him or her of the matters which form the subject of the arbitration. The Secretary-General of the Permanent Court of Arbitration shall take this information into account in making any appointments to the tribunal.

6. The function of an arbitral tribunal is to make an objective assessment of the matters which are the subject of the arbitration and to make such findings and rulings necessary for the resolution of the matters referred to it as it thinks fit. The arbitral tribunal shall release to the Parties its findings and rulings in a report on the matters referred to it within 180 days of its formation or such other period as the Parties may agree. The findings and rulings of the arbitral tribunal shall be binding on the Parties and the Parties shall take all necessary action to implement the rulings.

7. Unless the arbitral tribunal determines otherwise and subject to the provisions of this Annex, the arbitral tribunal shall be guided by the procedures in the UNCITRAL Arbitration Rules adopted by the United Nations Commission on International Trade Law

on 28 April 1976 as approved by the General Assembly of the United Nations on 15 December 1976.

8. Unless the arbitral tribunal decides otherwise, the expenses of the tribunal, including the remuneration of its members, shall be borne by the Parties in equal shares.

9. The arbitral tribunal may at any stage of the proceedings make proposals to the Parties with a view to achieving a mutually satisfactory solution of the dispute. The Parties may agree to terminate the proceedings of the arbitral tribunal in the event that a mutually satisfactory solution to the dispute has been found.

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

REGULATION IMPACT STATEMENT

In December 2003 the Australian and New Zealand governments signed a treaty to establish a single harmonised scheme for the regulation of therapeutic products[1] in Australia and New Zealand, to be administered by a single agency in both countries.

In 2000 the Australian and New Zealand governments made the "in principle" decision to establish such a scheme, subject to consideration of more detailed analysis of its net benefits. Cost benefit analyses in the form of Regulation Impact Statements were subsequently provided to both Governments. In late 2002 the Australian government agreed to commence implementation of the harmonisation of Australia and New Zealand's regulatory requirements for therapeutic products.

This Regulation Impact Statement (RIS) has two parts. Part 1 focuses on the costs and benefits that were considered when the decision was made to proceed to implement a harmonised scheme to be administered by a single joint Agency. It therefore reflects the situation in Australia and New Zealand in 2002 in relation to therapeutic products. Part 2 is designed to assist consideration of the content of the proposed Treaty between Australia and New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products.

PART 1 - HARMONISATION

1.1 BACKGROUND

Under the Trans-Tasman Mutual Recognition Arrangement (TTMRA), therapeutic goods[2] have a special exemption from the TTMRA on condition that Australia and New Zealand engage in a trans-Tasman co-operation program. Under such a program the regulators of the two countries are to collaborate to resolve the exemption which in this instance has been extended to May 2004. Options for resolution include mutual recognition, harmonisation or permanent exemption from the operation of the TTMRA.

In 1999 Australian and New Zealand Health Ministers agreed that formal harmonisation of regulatory requirements was the option they wished considered. This was to include

---

[1] "Therapeutic products" means products that are used or represented to prevent, diagnose, alleviate, cure or monitor a disease or condition, and comprises medicines (including medicines referred to as complementary health care products and dietary supplements in New Zealand), medical devices and other products such as some sunscreens, blood and blood components.

[2] that is, therapeutic products (the term "therapeutic goods" is used in the TTMRA legislation).

alignment of product and manufacturing standards and conformance assessment requirements. In 2001, they supported exploring particularly the feasibility of establishing a joint agency to regulate therapeutic goods[3] and policy development in this area proceeded (see under *Consultation* below).

Harmonisation through a joint agency arrangement has broad significance for closer economic relations (CER) between Australia and New Zealand. It may be an important precedent for any future development of joint agencies. The successful establishment and operation of this agency should significantly influence the attitudes of both governments regarding any future extension of CER.

Existing regulations

Legislative responsibility for the quality and safety of therapeutic products in Australia lay fully with States and Territories until the *Therapeutic Goods Act 1989* (the TG Act) came into force in February 1991. This created new national legislation where Commonwealth powers applied and where there had previously been only separate non-uniform State laws. It consolidated these provisions with the drug evaluation activity that the Commonwealth was already undertaking. The TG Act and its associated Regulations cover medicines, medical devices[4] and complementary medicines[5]. Unincorporated entities, such as pharmacists operating as sole traders, are currently not covered by the TG Act in Victoria, Queensland, South Australia, the Northern Territory and the ACT.

The subject matter of this particular national legislation is administered by the Therapeutic Goods Administration (TGA). TGA is a business unit within the Commonwealth Department of Health and Ageing, with a staffing complement, including non-ongoing staff, of approximately 440 persons engaged in the regulation of therapeutic products[6]. It operates on a full cost recovery basis with an annual budget of around $50 million collected primarily through annual charges, evaluation fees and licence charges.

In New Zealand, different arrangements exist for the regulation of pharmaceuticals, medical devices and complementary health care products. Pharmaceuticals are regulated under the *Medicines Act 1981* and the *Misuse of Drugs Act 1975* by Medsafe, a business unit of the New Zealand Ministry of Health. Medsafe is responsible for administering these statutes and regulations made under them. It has a staff complement of 56 and an annual budget of $6.9 million. Of this amount, $3.5 million is Crown funding and $3.4 million is third party revenue from fees and charges.[7]

---

[3] Therapeutic Goods Co-operation Program Reports to the Council of Australian Governments including New Zealand of 1999 and 2001 respectively.

[4] These include a very wide range of products from rubber gloves, syringes and diagnostic kits, to prostheses and implants such as pacemakers.

[5] These include herbal medicines, vitamins, minerals, nutritional supplements, aromatherapy oils and certain homoeopathic medicines.

[6] As at January 2004.

[7] As at January 2004 (figures provided by Medsafe).

With the exception of condoms and devices containing medicinal substances, medical devices are not subject to assessment in NZ. Medsafe's role is restricted to post-market monitoring with regard to other medical devices.

Complementary health care products in New Zealand are currently regulated as foods under the *Food Act 1981* and the *Dietary Supplements Regulations 1985*. No approvals for market supply are required unless therapeutic claims are made, in which case they are then categorised as medicines and subject to pre-market evaluation by Medsafe. Manufacturing premises for all complementary health care products must be registered under the *Food Hygiene Regulations 1974* as they are not currently required to meet Good Manufacturing Practice standards for medicines.

The nature of regulation of high and medium-risk pharmaceuticals in Australia and New Zealand is similar. However, low-risk pharmaceuticals, complementaries and devices are less closely regulated in New Zealand compared with Australia.

The Therapeutic Products Sector

The groups most affected by the issues under consideration are as follows:

- Consumers - and the wider community (including in regional areas) - Australia and New Zealand. The last National Health Survey for Australia that contained data about all medication use and not just use for specific conditions, was conducted in 1995, and found that in that year 51% of the population used medicines and 25.8% used vitamins and minerals, 9.4% used herbal and natural treatments and 33.4% consulted professionals in relation to health activity[8]. By 1999 the Household Expenditure Survey showed total annual household expenditure on medicines, pharmaceutical products, therapeutic appliances and equipment to be $2.997 billion[9].
- Industry – The industry comprises Australian and New Zealand therapeutic products manufacturers (prescription medicines, over-the-counter medicines, medical devices, complementary medicines) wholesalers and retailers. According to official statistics, the medicinal and pharmaceutical manufacturing industry in Australia had $4.594 billion of turnover and employed 12,500 persons in 1998, exporting some $1.26 billion of production[10]. There is also a large import sector ($3.016 billion) and an extensive distribution and retailing sector. According to estimates by industry analyst IBIS, this had grown to $5.8 billion turnover in 2000-01 with exports of $2.3 billion and imports of $4.7 billion.[11] For pharmaceuticals alone there are more than 120 companies in the industry, with the top ten accounting for 50% of sales[12]. The dominant firms are multi-nationals such as Astra, Merk Sharp and Dohme, Glaxo Wellcome and Alphapharm, but there is a small number of significant local companies such as Sigma and CSL. This sector overall had sales in 1999 of around

[8] Australian Bureau of Statistics, 4377.0
[9] Australian Bureau of Statistics, 6535.0
[10] Australian Bureau of Statistics. Op cit
[11] Ibis World, C2543 – Medicinal and Pharmaceutical Product Manufacturing in Australia, 20 November 2001
[12] Australian Pharmaceutical Manufacturing Industry Association Inc, APMA Facts Book – 1999-2000.

$8.94 billion, with $6.44 billion in pharmaceuticals, $1.06 billion in complementaries, and $1.5 billion in medical devices[13]. Data on the size, numbers and types of firms operating in each other's markets are not available.

- Sector representation - is found through bodies such as Medicines Australia (MA), the Australian Self Medication Industry Group (ASMI), the Complementary Healthcare Council (CHC) and the Medical Industry Association of Australia (MIAA). There is also consumer representation including through the Consumers' Health Forum of Australia (CHF) and the Australian Consumers Association (ACA). Professional groups, particularly in the medical, dental and pharmacy areas, are also seen as stakeholders in these matters.
- Government –Australian, State/Territory, local and New Zealand governments are involved. For Australia, government not only regulates this sector under the TG Act and related legislation but spends significant amounts on the products of the sector. For example, the Australian Government paid $3.07 billion in consumer pharmaceutical benefits in 1999 and further payments are made to industry under the Pharmaceutical Industry Investment Program. The Australian Government is the lead government for these purposes, but coordinates with the States and Territories through Ministerial Councils and committees of officials.
- Trade – trans-Tasman trade in therapeutic products comprises exports from Australia to New Zealand of the order of $208 million and imports from New Zealand to Australia of the order of $75 million. This represents a total volume of trade approaching $300 million annually[14].

Scope of regulation review for therapeutic products

In Australia and New Zealand, the major forms of regulation within the therapeutic products area are:

- Pre-market assessments, licensing of manufacturers and post marketing monitoring and enforcement of compliance with standards;
- Scheduling of chemical substances and associated controls to control access to, and supply of, therapeutic products;
- Monopsony purchasing of pharmaceuticals through government so as to subsidise prices paid by consumers and to facilitate product availability;
- Intellectual property and patent life rules and other industry development regulation (such as parallel importation controls) to enhance innovation in provision of therapeutic products and industry development.

Purchasing arrangements, intellectual property and patent life rules are outside the scope of the proposed trans-Tasman regulatory arrangements for therapeutic products and are therefore not addressed in this RIS.[15] This RIS also does not address issues of legislative

[13] Regulatory Impact Analysis, ~~A single joint Australia and New Zealand therapeutic goods agency,~~ October 2000, New Zealand Institute of Economic Research (NZIER), p25.

[14] Ibid, p51.

[15] Thus, in economic terms, intellectual property and related rules (eg parallel importing controls) address the firm spillover market failure in relation to product innovation; purchasing controls address the access

or regulatory reform to Australian regulation of therapeutic products beyond the trans-Tasman issue, since such issues have recently been the subject of separate review processes within Australia.[16]

1.2 PROBLEM IDENTIFICATION

Removal of barriers to trade and commerce

By their nature separate regulatory controls on therapeutic products restrict trade and/or duplicate effort relative to a common market without such controls. The general presumption of regulation review is that regulatory barriers should be removed unless there are market failure or other public interest reasons to the contrary. Where the barriers are divergent in content and process then firms incur the costs of operating under two systems with different characteristics. Even with the same characteristics simple duplication of processes can be costly.

The costs for business of lack of uniformity can be seen as falling into two broad categories:

- those associated with identifying and staying up to date with the requirements in each jurisdiction: and
- those where there is need to comply with different controls imposed by different jurisdictions.

Nature of market failure

One form of removal of barriers would be to remove regulation altogether in both Australian and New Zealand markets for therapeutic products and pursue free trade. This is not under consideration as market failure in these markets is well recognised. This derives in particular from:

- *information asymmetry* – where sellers have greater information and knowledge than buyers in this market to the detriment of consumers;
- *consumer externalities* - where improper use of these substances could result in detriment to other individuals and the wider community, and vice versa for proper use.

These problems are not removed even in the presence of increased public information, increased average education levels, and professional intermediation (though these help

---

and equity market inadequacy issue; scheduling and related controls address consumer information asymmetry (and sovereignty) and community externalities at point of purchase.

[16] *Review of Therapeutic Goods Administration*, Department of Health and Family Services, 1997; Industry Commission Review of Devices, Departmental review of Complementary Medicines; *National Competition Review of Pharmacy*, 1999; National Competition Review of Drugs, Poisons and Controlled Substances Legislation, 2001, Productivity Commission Review of Cost Recovery.

greatly[17]) because of the existing and growing complexity of the products and their potential to cause harm to health and safety if used inappropriately.

Protection of public health and safety

The appropriate degree of regulation in these matters for Australia has been the subject of separate review processes within Australia (see footnote 16 above). The outcomes of these reviews must here be assumed to be reflected appropriately in Australian regulation. Accordingly, the issue for health and safety in relation to trans-Tasman regulatory reform is to ensure that such reforms do not diminish previously agreed Australian regulatory standards - unless other compensating economic or public interest benefits are shown to arise from new trans-Tasman arrangements.

Differences in Australian and New Zealand Therapeutic Products Regulation

Australia and New Zealand use a broadly similar approach for the regulation of pharmaceuticals consistent with global harmonisation initiatives. Nevertheless, there are still some significant differences in the scope and the detailed operation of their current regulatory regimes. The unresolved differences in regulatory regimes have been the key reason for the continuing special exemption under TTMRA arrangements, reflecting the complex nature of these commodities in turn and their particular public health and safety dimensions.

The differences between New Zealand and Australia that underpin arguments for benefit from the elimination of difference, such as discussed above, are essentially the following:

(a) Limited coverage of New Zealand's existing regulation

Although much harmonisation between Australia and New Zealand's requirements already exist, both bilaterally and under global initiatives, New Zealand's current approach to therapeutic products regulation is generally not as comprehensive and consistent as Australia's e.g:

- divergence on some specific high risk and medium risk medicines;
- divergence of approach to regulating some aspects of lower risk and over the counter medicines;
- absence of pre-market regulation for most medical devices regulated in Australia; and
- divergence on direct-to-consumer advertising regulation.

(b) Differences in Regulatory Processes

New Zealand processes of regulation also diverge from Australia eg

- treatment of complementary medicines under food not medicines regulation, including in relation to manufacturing standards; and

[17] The legislative and regulatory arrangements under consideration here for harmonisation in relation to therapeutic products do not extend to legislation regulating professional practice.

- limited enforcement of pre-market evaluation requirements even where therapeutic claims are being made for complementary medicines.

These differences of coverage and process imply two major issues. The first is that differences in the administration of the regulatory processes in the two countries created trade barriers[18], so inhibiting the achievement of the objective of the CER trade arrangements as regards these industries. The second is that even simple duplication of common regulatory requirements for medicines creates additional compliance costs for businesses operating in either or both of the two markets. Such costs could be lower with pooling of resources in the presence of common standards[19].

(c) Regulatory Sustainability

One possible gain from harmonisation and elimination of regulatory duplication is the ongoing sustainability of the regulatory capacity and skills in both Australia and New Zealand. [20] The evaluation of new and innovative therapeutic products is becoming increasingly complex, and the pool of skilled resources available to the regulators is diminishing. [21] In New Zealand, lengthening of processing times for pre-market evaluations and the lack of skilled resources to process some complex products (eg genetically modified vaccines) is already being experienced.[22]

Rapid change is being driven by competition, innovation and emerging technologies. For example, the pharmaceutical industry predicts the workload for regulators over the next few years will rapidly increase due to the industry's heavy investment in research and development (R&D) [23]. From 1986-1996, R&D expenditure in the Australian pharmaceutical industry rose sixfold, and its investment in R&D represents 5.5% of its production income. By contrast, the general manufacturing sector invests only 1.1% of its production income in R&D[24].

There has been a consequential burgeoning of new pharmaceutical products entering the market in recent years. The total number of applications to the TGA for product approval increased by almost 50% over the financial years 1995-6 to 1998-9[25]. The strongest growth is evident in applications for approval of high risk medical devices, which increased by 100% over the same period. This very high rate may be due in part to a

---

[18] NZIER, op.cit, p17.

[19] The precise number of firms operating in the two therapeutic products markets is unclear, but it will be recalled that the costs impact on a present volume of Trans-Tasman trade in therapeutic products of around $300 million annually and rising (NZIER, op.cit. p51.)

[20] Report of the Regulatory Reform Taskforce, Review of Administrative Arrangements for Commonwealth Public Health and Safety, Department of Health and Aged Care, August 2001, pp.155-161

[21] Commonwealth Department of Health and Aged Care, *Annual Report 2000-2001*, p.378.

[22] Loc Cit

[23] Gunnaway, DJ, "Future Challenges for Drug Regulatory Agencies", *Presentation to International Conference of Drug Regulatory Authorities*, 1999.

[24] Australian Economic Analysis, 1998

[25] Department of Health and Aged Care, *Annual Report*, 1999.

classification change, but high rates were nevertheless evident for all therapeutic products.

(d) Regional and Global Status Issues

A final set of issues revolve around regional and global concerns. These reach beyond narrow economic trade and administrative cost considerations. They are also even harder to demonstrate and quantify, partly because they depend upon strategic considerations that are not deterministic in the manner of some of the simpler competitive economics that often inform benefit-cost analysis. That does not render them less real nor make them irrelevant to a regulation review, as they potentially involve broader public benefits for Australians. Three claims seem pertinent:

- in the trans-Tasman arena the proposals for a joint administrative decision-making agency offer new possibilities for even greater integration in other areas between the two systems than simply that of removal of barriers. If the various legislative, political and administrative considerations are successfully addressed, an important precedent and set of "public good" knowledge for similar joint ventures is created;

- in the global therapeutic products industry, pooling of two previously sovereign markets under a common regulatory framework of high quality, may have symbolic impact beyond the simple advantages of a bigger common market. In particular, pharmaceutical companies attach importance to approvals and hence first release of new products in countries acknowledged as benchmark regulators for quality. It is arguable that a joint agency will help sustain Australia's reputation and position as a so-called "first wave" country for such purposes, with consequent benefits to consumers; and

- success in harmonisation in this complex field for Australia and New Zealand may induce other nations to seek to join the arrangement or to adopt its standards, particularly in the Asia Pacific.

1.3 OBJECTIVES

The special exemption that therapeutic products have from the operation of the TTMRA must be resolved in a way that:

- safeguards public health and safety in Australia and New Zealand by efficiently and effectively regulating therapeutic products in both countries; and
- avoids barriers to trade except where they are necessary to safeguard public health or safety.

1.4 REGULATORY OPTIONS

Options for resolving the TTMRA special exemption for therapeutic products included mutual recognition of Australia and New Zealand's regulatory standards, harmonisation

of standards or, failing either of these options, permanent exemption from the operation of the TTMRA. Because of the significant differences in regulatory approach, including the different standards that applied to some product groups, mutual recognition was considered unacceptable. Work therefore focussed on the two remaining options that are discussed in more detail in the following paragraphs. In the interim, the special exemption has been renewed annually, following consideration of progress reports on the work being undertaken.

1.4.1 PERMANENT EXEMPTION

This option extends the status quo for Australian arrangements, with therapeutic products being regulated under the current Australian legislation. It elects to adopt a permanent exemption for the regulation of therapeutic products under the TTMRA. Within this option of permanent exemption, account should be taken of the likely effect in Australia of New Zealand's own principal alternatives to harmonisation, viz:

a) the adoption of a system based on limited domestic evaluation but wide unilateral recognition of pharmaceuticals, complementary medicines and therapeutic devices approved by other specified regulatory authorities;
(b) the adoption of a new enhanced regulatory framework with local evaluation of products to international standards and no necessary particular harmonisation with Australia; and
(c) the status quo ie limited regulatory coverage of complementary medicines and medical devices within existing and likely diminishing evaluation capability.[26]

In terms of change, only (a) and (b) are relevant.

1.4.2 HARMONISATION

This option entails a single harmonised regulatory scheme in Australia and New Zealand to be administered by a single joint trans-Tasman regulatory agency that would replace TGA in Australia and Medsafe in New Zealand (the Agency). A Treaty between the two countries would set out how the Agency would be established under Australian legislation, and its operational framework, including establishment of a Ministerial Council comprising the Australian (Commonwealth) and New Zealand Health Ministers and a five member board responsible for the strategic and administrative direction of the Agency.

The Agency would regulate the full range of therapeutic products ie prescription medicines, over the counter and complementary medicines, medical devices and other therapeutic products including some sunscreens and blood and blood components. Its functions would include pre-market evaluation/assessment and approval, licensing the manufacture of products, scheduling, product standard setting, advertising, post-market monitoring and surveillance. Offices would be established and maintained in each country to provide a local point of contact with the Agency.

---

[26] NZIER, op cit.

A Managing Director, appointed by the Ministerial Council, would be responsible for regulatory decisions in much the same way as the Secretary of the Department of Health and Ageing is currently responsible under existing Commonwealth legislation. In practice, the Managing Director would delegate the power to make certain decisions to persons with the appropriate expertise and/or functional responsibility. Expert advisory committees would provide advice to the decision-maker.

At the time the joint Agency approach was decided upon, it was contrasted with the one other precedent in this field, the model offered by the Australia New Zealand Food Authority (ANZFA), now Food Standards Australia New Zealand (FSANZ).

The proposed Agency model varies substantially from the ANZFA model principally because of the marked difference between the respective roles of the two agencies.

ANZFA operated as an Australian statutory agency established under Australian legislation. It was responsible for setting and varying food standards that are then adopted and enforced by the States and Territories in Australia and by a separate Foods Safety Authority in New Zealand. ANZFA does not itself enforce compliance with standards in the various jurisdictions.

In contrast, the Agency will administer a single, joint regulatory scheme that will be equally applicable in both countries. The new agency will regulate the import, export, manufacture and supply of therapeutic products in two independent and sovereign countries through pre-market assessment of products, licensing of manufacturers and post market monitoring of compliance with and enforcement of standards. The Agency will make decisions on behalf of two independent and sovereign Governments in relation to therapeutic products and will be empowered to enforce those decisions in both countries. The Agency will be established in Australian legislation but, unlike FSANZ, the Agency will also be empowered to act in New Zealand through legislation in that country.

Under this model the Agency must be equally responsive to both the Australian and New Zealand Governments with neither having the opportunity to unilaterally make decisions or issue directions that could adversely impact the interests of the other.

1.5 ASSESSMENT OF IMPACTS

In assessing impacts of options it is important to recognise that the proposals relate to relatively small agency costs, compared to industry size. TGA is a $50 million per annum agency and Medsafe is a less than $7 million per annum agency. The relevant industry represents around $9 billion in sales in Australia and $1.5 billion in New Zealand. The repercussions of harmonisation here are to that extent limited in overall magnitude. In addition, they will mostly be limited to benefits in respect of trade, estimated to be in the order of $300 million.

Much analysis of impact is of necessity qualitative without detailed quantification or modelling, since large scale economy-wide effects are not likely or discernible. Illustrative or descriptive data are nevertheless used wherever available and appropriate.

OPTION ONE – PERMANENT EXEMPTION

Under Option 1, permanent exemption for therapeutic products under the TTMRA, New Zealand faces three possible choices:

A.- to implement new legislation to cover all complementary medicines and medical devices, with ongoing unilateral recognition of market approval in overseas countries;
B.- to implement new legislation to operate a stand-alone regulatory system to international standards across the full range of therapeutic products; or,
C.- to maintain current New Zealand regulatory arrangements without change.

A. If **New Zealand implements new legislation** to cover all complementary medicines and medical devices, **with ongoing unilateral recognition** of market approval in overseas countries, then the impacts on Australia will be as follows:

Benefits

Australian business: where New Zealand recognises Australia's regulatory approval, there will be reduced compliance costs for those Australian businesses (particularly in the pharmaceutical sector) which currently have to go through any additional approval process for New Zealand. The number of Australian firms which export therapeutic products to New Zealand has not been documented. However, Australian exports are estimated to be of the order of $208 million, compared with sales in Australia of around $9 billion. Exports to New Zealand therefore represent roughly 2.3% of Australian sales.

There will be new transitional marketing opportunities to New Zealand for those firms in the medical devices and complementary medicines sectors which already have approval in Australia. These Australian firms may have an early competitive advantage over New Zealand firms now seeking local approval for new products.

Australian consumers: some additional direct benefits from greater product safety in New Zealand, but where Australian firms have reduced compliance costs, they may pass these on to consumers in competitive markets as lower prices for their products.

Australian government: there may be a very small amount of income flowing as a result of New Zealand contracting TGA to undertake evaluations on its behalf for New Zealand manufactured products. However, Medsafe estimates this to be insignificant, with only 2 or 3 applications per year[27], down from an average of 30 applications per year in past years since other countries' approvals will also be accepted.

[27] Medsafe, email, 5/12/01

Costs

Australian therapeutic products industry: Where New Zealand chooses to recognise overseas approvals other than from Australia, then there would be reduced marketing opportunities to New Zealand for Australian firms. Australian exporters to New Zealand would face increased regulatory and compliance costs for complementary medicines and devices which will now require registration or listing in New Zealand. They will also face greater competition from overseas firms with product approvals already recognised by New Zealand.

Australian consumers: Australian residents travelling to New Zealand may purchase and use therapeutic products, which may now be higher in cost due to the expanded scope of New Zealand regulation under this option.

Australian government: no new costs over status quo.

B. However, if **New Zealand implements new legislation to run a stand-alone regulatory system to international standards across the full range of therapeutic products**, then the further effects on Australia will be as follows:

Benefits

Australian business: no additional benefits over status quo.

Australian consumers: no additional benefits over status quo.

Australian government: no additional benefits over status quo, as this is a continuation of current arrangements for TGA.

Costs

Australian business: Australian firms that export medical devices and complementary medicines which are not currently subject to regulation in New Zealand, would face increased regulatory and compliance costs. Australian evaluation standards may be recognised, but differences in scheduling, packaging, labelling etc are likely to still occur and simple documentation and processing incurs fees, costs and delays even where difference is not present, including in pharmaceuticals.

Consumers: the likely increased costs to Australian business may flow through in part to increased costs to consumers.

Australian government: no new costs over status quo.

C. If **New Zealand does not change regulation of therapeutic products, from current arrangements,** then the effects on Australia under a permanent exemption will be as follows:

Benefits

Australian business: no change

Australian consumers: no change

Australian government: no change

Costs

Australian business: no change

Australian consumers: no change

Australian government: no change

In principle, under the status quo, Australian production and consumption patterns for therapeutic products, and trans-Tasman trade, will develop according to industry and economy imperatives without impact from regulatory change in Australia and New Zealand under TTMRA affecting this.

Other reviews of existing Australian legislation and regulation of therapeutic products (see footnote 16) have examined this regime. It has been affirmed that it meets the test of benefit exceeding cost and of being the least costly form of meeting the regulatory objectives. Some particular reforms are under consideration by government, but they do not constitute proposals for fundamental system change.

However, there is a strongly expressed view in New Zealand that the regulatory status quo there is "unsustainable"[28], and that permanent exemption Options A and B above are more realistic prospects.

OPTION TWO – HARMONISATION

This is the option that was agreed to by both Australia and New Zealand.

Economic Efficiency Impacts: Quantification

The major prior quantification of the economic efficiency benefits from trans-Tasman harmonisation was provided in the earlier NZIER study which estimated that adding New Zealand's market to Australia's on the same terms as for the existing Australian domestic market could deliver potential one-off productivity benefits for the sector of between 2 to

[28] NZIER, op cit, iii.

3 per cent, or $180-270 million[29]. Despite a total trans-Tasman trade only of the order of $300 million, such productivity benefits are, in principle, feasible if they come from a small percentage scale economy gain applied across domestic as well as export production.

The proposed regulatory changes are expected to have a beneficial impact for Australian industry through a reduction in industry compliance costs. The establishment of a single trans-Tasman market for therapeutic products through harmonisation opens export opportunities for the Australian industry that otherwise might not be feasible. It will no longer be necessary for the Australian industry to maintain resources with expertise in the two separate country regulatory requirements or to submit two separate country applications for marketing approval. It will no longer need to meet two different standards of scheduling of medicines and medical devices, or different labelling, packaging and advertising requirements in particular. A single application for marketing approval can be submitted to the Agency that, once processed, will provide an opportunity for quicker market access in two countries rather than one, thus impacting positively on the company 'bottom line'. Consumers will benefit through earlier access to therapeutic advances and a possibly expanded range of products in the marketplace.

Precision in estimating the economic benefits to Australian industry is not possible due to the lack of readily available and relevant data.

Specific savings have been suggested as follows under harmonisation:

Figure 1 **Compliance Activity Scenarios: Trans Tasman Harmonisation[30]**
Scenario 1: Registration of an OTC medicine in Australia and New Zealand currently involves payment of two registration fees. A single fee would be less than the two separate fees.
Scenario 2: Different regulatory requirements in both countries require that different labelling be produced for many products which are otherwise identical. Harmonisation would reduce those costs to business substantially
Scenario 3: Different regulatory requirements in both countries require that different packaging types or sizes (e.g. different number of dose units per blister platform) be produced for many products which are otherwise identical. Harmonisation makes for much more efficient production processes.
Scenario 4: Regulatory staff required to be maintained in one or both countries to cover different regulatory requirements. A staff saving of 1-2 persons saves each company $100k-$200k annually.

[29] NZIER, op cit.
[30] Source: Australian Self-Medication Industry, correspondence, January 2002.

Scenario 5: Different regulatory requirements in both countries require that advertising be modified to suit each country's unique requirement. A significant saving in business costs can result.
Scenario 6: A joint agency regime would provide the opportunity for companies marketing products only in Australia to also enter the New Zealand market for very little extra investment.
Scenario 7: Under the current arrangements, more lightly regulated NZ dietary supplements are imported into Australia and potentially erode the more highly regulated Australian complementary medicines market. A level playing field would assist Australian industry.

Administrative Efficiency Impacts: Quantification

The Agency will be required to report to both the Australian and New Zealand Governments and to meet any necessary mandatory standards in both countries. Discussions with respective national agencies are aimed at eliminating unnecessary duplication and reducing associated costs.

Over time, harmonisation is expected to move beyond mere adoption of uniform regulatory coverage, standards and processes to embrace reduction or removal of duplication for common systems, where this exists. This provides an option for administrative efficiency gains to be made. Where regulatory systems and associated administrative processes are developed de novo for activities not currently regulated in New Zealand, particular care will be taken to ensure streamlining for efficiency and effectiveness.

As regards transitional issues, the change from TGA to the Trans-Tasman Agency will have significant associated costs for which government has provided funds, some of which is to be recovered from industry (see below under the heading *Funding of the Joint Scheme* in Part 2 of this RIS).

Other Impacts

The issues raised in terms of impact of trans-Tasman harmonisation for therapeutic products on regional and global governmental and industry outcomes are more difficult to quantify but appear to offer the exciting potential for ground-breaking work in developing arrangements that could support future joint regulatory endeavours.

Review of Separate Harmonisation Options

A. TRANS TASMAN THERAPEUTIC PRODUCTS AGENCY

The analysis of benefits and costs for the single joint agency proposed is considered against the current arrangements for TGA and Medsafe, and assumes that pharmaceutical pricing policies and patent policies in each country remain unchanged. The Agency proposal is for comprehensive coverage of the full range of therapeutic products in both countries. However, the precise degree of benefit and cost will vary with the implementation time path adopted and the extent to which opt-out provisions in the Treaty are exercised (see Part 2 of this RIS for an explanation of the capacity of Australia and New Zealand to each determine, in exceptional circumstances, that they will not regulate specified therapeutic products under the harmonised scheme).

Benefits

Australian business: That part of the therapeutic products industry that exports to New Zealand (approximately 2.3% of Australian sales) will benefit from reduced compliance costs due to single applications rather than dual applications and faster turnaround times. This means that industry will only have to face one application and/or evaluation fee to gain access to two previously separate markets - a world first in therapeutic products regulation. Common packaging, labelling and advertising requirements will apply in Australia and New Zealand. This will mean compliance costs to operate in two markets will be lower. These cost effects will vary with the nature of business but may be particularly important for some business types, eg small trans-Tasman export and import firms with a large product range.

Industry will benefit financially from having products on the market earlier with the potential for enhanced profit. All products currently registered only in one country will also benefit from increased market opportunities.

Consumers: It is expected that Australian consumers will gain earlier access to therapeutic products at a reduced cost as industry passes on costs savings and has products on the market earlier.

Governments: In the longer term, if the joint agency helped better establish Australia as a regional centre for therapeutic product regulation, it might also thereby enhance investment, the manufacturing base, and Australia's potential for exporting.

The creation of the joint agency will provide opportunities for suppliers of therapeutic products to consider Australia and New Zealand as a single market. Over time, this would lead to the greater trans-Tasman integration of business operations and strategies, which is one of the aims of CER. This may serve as a 'blue print' for future cooperation in the Asia Pacific region.

With a single regulatory system, Australia and New Zealand are better placed to influence global and regional standards, for example by seeking admittance to fora such as the International Conference of Harmonisation (ICH) process for pharmaceuticals. It might also be the case that other regional countries might seek to join an Australasian system.

Some economies of scale will be available for the regulator through a combined operation and market, and through other synergies such as allowing greater pooling of technical expertise, permitting greater opportunities for career development, flexibility and specialization. [31]

Given the increasing pressure of demand for the high level complex expertise required for approval and registration of therapeutic products, a pooling of scarce and expensive technical expertise within an integrated agency would provide both countries with assistance in addressing this problem in the medium to long term. Other mechanisms will also help greater global co-operation and harmonisation in this field, but a common pressure is evident: "Science is producing new wonder drugs faster than we can work out how to pay for them"[32]

Costs

Australian business: In the short term there will be increased fees and charges to cover some of the transitional costs such as developing an integrated registration system. This would include the cost of government recovering $7 million from industry over a period of 5 years[33]. However there is an "efficiency dividend" from reduced administrative duplication that in principle is available to fund transition with suitable funding arrangements negotiated with government so as to avoid short term hikes and reversals in fees.

Consumers: no new costs to Australian consumers unless any transition costs in excess of short term benefits exist and are passed on to consumers in prices.

Government: full cost recovery principles are stated to apply, so no budget cost to government is involved.

---

[31] The importance of enhanced regulatory capacity is illustrated in a report on the PBAC decision-making processes. In relation to a decision on a new rheumatoid arthritis drug, Enbrel, it was said that "Biotech drugs are not new. Insulin has been produced in a similar way for more than two decades. What is new is the incredible complexity of many of the drugs. When compared to insulin, the molecular structure of etanercept (Enbrel's generic name) looks like a cruise liner moored alongside a tugboat." Stephen Brook, "Bones of Contention", *The Australian*, February 2-3, 2002, p.24

[32] Ibid

[33] See under Funding the Joint Scheme in Part 2 of this RIS for more details.

B. THE AUSTRALIA NEW ZEALAND FOOD AUTHORITY (ANZFA) MODEL

One alternative option for harmonisation is the model of the previous food authority, ANZFA (now FSANZ). This model was in operation in 2001. An assessment of the benefits and costs of this model follows.

Benefits

Overall, this model will help to remove regulatory barriers to trans-Tasman trade in therapeutic products as it provides a focus for cooperation between governments, professionals, industry and the community in the regulation of therapeutic products.

Business: benefits are likely for a single agency compared with the status quo, but with less guarantee of the degree of harmonisation both in principle and in practice, as the co-operation of jurisdictions is discretionary (not grounded in a legislative commitment) and the implementation is in the hands of separate arrangements that can develop processes that differ.

It will reduce compliance costs for those Australian businesses (manufacturers, wholesalers, retailers) seeking approval to market approved Australian products in New Zealand, because one application and evaluation would suffice for both countries.

Consumers: will benefit to the extent the harmonisation reduces compliance costs and the costs are passed on.

Government: can better meet general CER objectives than with exemption and retain greater sovereignty than with a single agency - though opt-out provisions, if relied upon in the latter do still allow some independence and localisation.

Costs

Australian business: Under the ANZFA model, ANZFA made recommendations to a Ministerial Council regarding food standards, and the Council had to adopt those standards before they were adopted into the law of the various jurisdictions. If this model was followed, the time taken for products to be approved (whether registered or listed) will be extended considerably because the agency could only make recommendations for approval to the Ministerial Council, and it would need to be approved by the Ministerial Council and undertake some administrative step (eg gazettal) before it would have effect. This would take some time as the Ministerial Council would not realistically meet other than periodically.

This would result in a longer time lag between an application and final approval to market, thus reducing the period of profitability, compared to the current regulatory system. This is a highly competitive industry sector, with new products and variations/improvements to devices having ever shorter developmental phases.

Businesses are dependent on an efficient approvals process to get their products to market before their competitors. It is likely that major global producers of therapeutic products, particularly in the areas of pharmaceuticals and highly complex devices, would avoid applying to market their products in Australia and New Zealand.

Consumers: may not have as timely access to products as under either the status quo or a single agency, and will not have potential for as much cost reduction flow through as with a single agency.

Governments: Ministers, as decision-makers, would have a huge workload in determining approvals, as TGA and Medsafe together approve a very high volume of products each year. Even if the Ministers met in Council frequently, their role as regulatory decision-makers would still take up a considerable amount of time away from their main responsibilities. Under the more recent FSANZ food regulatory model, this cost would fall particularly heavily on those Ministers whose portfolios were not in the health area. Ministers' workloads would also be exacerbated if they made decisions in relation to individual approvals and those decisions were appealed against by aggrieved applicants and subjected to administrative review.

The costs of establishing a Board of approximately 10 members, as in the ANZFA arrangements, to regulate therapeutic products would also be substantially higher than a Board of 5 members as proposed under the joint agency arrangements, though this could no doubt be negotiable. Still involving industry and consumer representatives in the approval process, and decision-making at the political level, may lead to more conflicts of interest, giving rise to more appeals against regulatory decisions. These increase the direct cost to governments, as well as to industry, and are thus likely to result in flow-on increases in charges for applications and in consumers paying increased costs for therapeutic products.

SUMMARY OF OUTCOMES FOR EACH OPTION

Figure 3: RIS Summary of Impacts

OBJECTIVE : To review options for regulation of trans-Tasman trade in therapeutic products, so as to enhance trade, industry and health

Option	IMPACT ON AUSTRALIAN			Likely benefit/comments
	Consumers	Business	Government	
1.Permanent Exemption				
A. New Zealand Unilateral	No change in product standards, availability and price in Australia.	Increased compliance costs and marketing competition for Australian firms in the New Zealand market.	Loss of prestige and influence in international regulatory and trade if New Zealand does not recognise Australian approvals.	Minimal impact on Australia.

OBJECTIVE : To review options for regulation of trans-Tasman trade in therapeutic products, so as to enhance trade, industry and health

Option	IMPACT ON AUSTRALIAN			Likely benefit/comments
	Consumers	Business	Government	
B. New Zealand Stand Alone	No change in product standards, availability and price in Australia.	Increased compliance costs for Australian firms seeking market approval in New Zealand.	Some small agency savings through no longer providing free evaluations to NZ.	Minimal impact on Australia.
C. Status Quo	No change in product standards, availability and price in Australia.	No change in compliance costs for Australian business	No change in government impacts for Australia.	Makes permanent the current exemption arrangements.
2.Harmonisat-ion				
A. joint Agency	No change in standards of products. Prices same or small decrease over time.	Enhanced market due to reduced compliance costs and fees for registration in both countries allowing more economies of scale and scope.	Improved economies of scale for regulators, but within full cost recovery environment. Longer term: Maintenance of regulatory capacity by pooling expertise; potential to establish Australia as regional centre for therapeutics regulation.	Removes trans-Tasman trade barriers, and provides greater net benefits for industry, consumers and governments compared to the alternatives considered. Preferred option. Provides greater economic efficiency, administrative efficiency and regional and global status.
B. ANZFA Model	Reduction in timely availability of all products, especially new prescription medicines and advanced devices.	Likely reduced compliance costs for Australian firms seeking market approval for New Zealand. Significant increases in approval times, likely to act as strong disincentive for major global producers to market new products in Australia.	Some reduced duplication in regulatory administration. Possible increases in appeals costs.	While it helps remove trans-Tasman trade barriers, full harmonisation and administrative integration is not guaranteed.

1.6 CONSULTATION

Australian and New Zealand officials have worked closely and consulted widely with stakeholders:

- Consultation was conducted with relevant Australian and New Zealand Government Departments, and the Regulatory Reform Taskforce.

- In June 2000 an initial consultation paper was released in Australia to the Liaison Group for Trans-Tasman Co-operation on Therapeutic Goods, which comprised representatives from the medicines and medical device industries, healthcare professional associations, consumers and key government agencies. 27 submissions were received in response.

- In October 2000, an initial report on the potential economic impacts of a joint Agency was prepared jointly by the New Zealand Institute of Economic Research (NZIER) and Applied Economics and released.

- In mid-2001, a Trans Tasman Project Team of officials from TGA and Medsafe was established, to progress the establishment of a joint agency.

- Industry consultations were held in the latter part of 2001, including a formal meeting in Sydney in December 2001 to discuss the release of a consultation paper prepared by the team entitled "Establishment, Governance and a Proposed Regulatory framework for a Trans Tasman Therapeutic Goods Agency" which was subsequently released on 17 December 2001 to a targeted group of Australian and New Zealand stakeholders. 24 submissions were received in response.

- Input into the development of the RIS that was provided to Government in February 2002 on issues relating to harmonisation was invited by earlier letter (including a survey questionnaire) and by direct follow-up both before and after the December 2001 meeting.

- A meeting with key stakeholders was held in Auckland in March 2002, at which further verbal comment was provided on the proposals - this meeting was followed by focus group meeting with key industry groups to discuss specific aspects of the regulatory framework.

- Based on the outcomes of the stakeholder feedback, a public discussion paper entitled "A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products" was published in June 2002 by the Commonwealth Department of Health and Ageing and sent to over 240 stakeholders. Letters publicising its release and seeking submissions were also sent to all sponsors of therapeutic products on the Australian Register of Therapeutic Goods. Forty written submissions were received from Australian stakeholder groups in response.

Overall, government, industry and consumer bodies are supportive of the proposed single joint agency. Some saw this as being beneficial for trade, while others highlighted the benefits of lower compliance costs flowing from a single entry point for product registration and approval processes. Particular issues raised are being taken into account in the development of the regulatory scheme and its framework.

1.7 CONCLUSION AND RECOMMENDED OPTION

Harmonisation through the establishment of a single joint agency is the preferred option to its alternative - making a special TTMRA exemption for therapeutic goods regulation permanent.

There are a number of key advantages for Australia and New Zealand in creating a joint agency for the regulation of therapeutic goods. A joint agency, involving a high degree of regulatory harmonisation, would:

- deliver greater efficiencies through reducing transaction costs of meeting different regulatory requirements and through reducing duplication where common requirements apply in separate jurisdictions. This will allow in turn improved economies of scale and related synergies which will facilitate trans-Tasman trade through the provision of common regulatory outcomes for the two countries, consistent with the broader objectives of Australia New Zealand Closer Economic Relations Trade Agreement (ANZCERTA). This will deliver improved domestic production and cheaper domestic supply to the extent that cost savings generated by merger efficiencies have any flow on effect other than to those firms exporting to New Zealand;

- deliver public health benefits for both Australia and New Zealand by creating an enhanced and sustainable regulatory capacity in the medium and longer term. This would assist the two countries to meet the increasingly difficult challenge of maintaining necessary regulatory capacity at current or higher standards in the face of the expanding range and increasing complexity of therapeutic products; and address the need to safeguard against a loss of critical mass in a highly technical and competitive field; and

- enhance the influence of each country in regional and global regulatory and trading environments. This would have the benefit of gaining greater global status for industry and global standards responsiveness to Australian local needs. It would also facilitate the potential for Australian standards and processes to influence the determination of global standards, thereby reducing adjustment costs for Australian agencies, industry and consumers.

The option of new permanent exemption arrangements is not a preferred option. It maintains the barriers to trans-Tasman trade in therapeutic goods, and hence forgoes trade and industry development improvement. Nor does it assist with the problems of

keeping up with demand expected from emerging technologies or maintaining regulatory capacity.

Ongoing costs under permanent exemption could actually be relatively higher for Australia than at present if New Zealand were to implement its option for new legislation as a stand-alone agency, or if it were to adopt the new legislation option with unilateral recognition of countries other than Australia. However, were New Zealand to adopt unilateral recognition of Australia, then the ongoing costs to Australia under the status quo would be lower.

Within a harmonisation approach, the ANZFA model is also not a preferred option. Compared with ongoing exemption, it would have the positive effect of trade and industry improvements through reducing regulatory barriers to trans-Tasman trade in therapeutic goods, but with less certainty and commitment than a joint Agency would achieve. It would most likely incur significantly greater costs in time taken for processing recommendations which have to be forwarded to Ministers for decision-making. It would also not deliver the full administrative efficiencies of avoiding duplication and pooling resources, as would a joint Agency. Implementation and enforcement would remain as separate responsibilities in Australia and New Zealand. Nor would it be as convincing to global industry and regulatory networks in terms of enhancing Australia's role or influence.

1.8 IMPLEMENTATION AND REVIEW

The Agreement Between Australia and New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (the Treaty) was negotiated in 2003 and signed in December 2003 as a first step towards implementing harmonisation (Option 1) through the establishment of a single joint Agency. The implementation and review of the arrangement agreed to under the Treaty is discussed further in Part 2 of this RIS.

PART 2 – THE PROPOSED TREATY

This second part of the RIS has been prepared to assist the consideration of the Agreement between Australia and New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (the Treaty) signed on 10 December 2003.

It analyses the proposed operational arrangements for the Agency provided for under the proposed Treaty under the following headings:

- the governance of the Agency;
- the accountability of the Agency;
- the legislative basis of the joint Scheme;
- merits review of Agency decisions; and
- departures from the joint Scheme.

2.1 BACKGROUND

The principle objective of the Treaty is to safeguard public health and safety in Australia and New Zealand by establishing and maintaining a joint Scheme (the Joint Scheme), consistent with international best practice, for the regulation of the quality, safety and efficacy or performance of therapeutic products, and of their manufacture, supply, import, export or promotion. Therapeutic products comprise prescription medicines, over the counter and complementary medicines, medical devices and other therapeutic products such as some sunscreens and blood and blood components. This part of the RIS outlines the key aspects of the Joint Scheme and analyses the impact they will have when the Treaty enters into force.

The proposed Joint Agency and Scheme

The Treaty specifies that a joint Agency (the Agency) will be established by Australian legislation, in the manner specified in the Treaty, to administer the Joint Scheme. The Agency is expected to commence operation in mid-2005 and will replace the TGA in Australia and the Medsafe Unit of the Ministry of Health in New Zealand.

The Agency will regulate the full range of therapeutic products manufactured or supplied in, or exported from, Australia and/or New Zealand to ensure they meet appropriate standards of quality, safety and efficacy. Its functions will include pre-market evaluation and approval, licensing and auditing manufacturers of products, post-market monitoring and surveillance, the oversight of advertising arrangements for therapeutic products, and the setting and monitoring of standards (eg quality and labelling). The Agency will function on a full cost recovery basis.

The Joint Scheme will be based on a risk management approach, in which the degree of regulatory control would be proportional to the risk associated with use of the product.

Products will be evaluated or assessed according to their risk, ranging from low risk products (most complementary medicines) to higher risk products (prescription medicines, vaccines and implantable devices).

Consistent with current Australian requirements, the Agency will issue product licences, and have the power to suspend and cancel product licences if sponsors breached compliance requirements. Each product will be uniquely identified, consistent with current practice in Australia, to ensure traceability of products in the event of product failure and the need for recalls, and to ensure that only licensed products (unless specifically exempted) are available for supply in Australia and NZ. The Agency will have sufficient enforcement and monitoring powers, including the power to request information, take samples for testing, search premises and seize goods, impose administrative sanctions and refer alleged offences for prosecution.

Reasons for the Joint Scheme

The reasons for establishing the Joint Scheme are set out in Part 1 of this RIS. In summary, by signing the Treaty, the Australian Government has decided that a joint Scheme with New Zealand for the regulation of therapeutic products should be established. It is anticipated that the Joint Scheme will:

- resolve the TTMRA special exemption for therapeutic products regulated under the Joint Scheme;
- meet the overall objectives of the ANZCERTA by facilitating trans-Tasman trade;
- ensure sustained capacity for the regulation of such products in Australia in the present and in the future;
- reduce industry compliance costs by increasing regulatory cost efficiency;
- benefit consumers by increasing the timely availability of therapeutic products potentially at a reduced cost; and
- provide Australia, together with New Zealand, with greater capacity to influence international regulatory policy and standards.

Funding of the Joint Scheme

In the 2003-04 Budget the Australian government agreed to provide $8 million (in the form of $5.4 million in 2003-04 and $2.6 million in 2004-05) for the 'establishment and implementation costs' of the trans Tasman proposal. $5.1 million was provided to the TGA to work in partnership with New Zealand officials to develop the Treaty, establish the joint regulatory framework (including community and industry consultation) and facilitate the establishment of the new agency. The remaining $2.9 million represented Australia's contribution to new financial, administrative and regulatory infrastructure that would be required by the joint agency to operate independently from both governments (to be matched by the New Zealand government). The infrastructure funding was appropriated to the TGA in 2003-04.

In agreeing to provide the additional funding, the Australian government assessed the case for cost recovery from industry. Activities relating to the drafting of the Treaty and

harmonisation were assessed as being in the nature of policy and ought not be recovered from industry (in accordance with Commonwealth Cost Recovery Guidelines for Regulatory Agencies). These activities were estimated to cost $1 million. The government subsequently agreed that the remaining $7 million would be recovered from industry over five years, commencing from 2005-06.

In addition to matching Australia's $2.9 million contribution to the infrastructure needs of the new agency, the New Zealand government has undertaken to resource its officials to participate in the development of the Treaty and the development of the regulatory framework, and has also undertaken to contribute $3.44 million towards a reserve fund to meet the working capital needs of the new agency (effectively matching the estimated balance of the TGA's reserves when the new agency is formed).

The impacts on industry of the changes to cost recovery, including consistency with the Government's cost recovery policy, will be addressed through a Cost Recovery Impact Statement prior to determining the final level and structure of the fees and charges.

2. 2 PROBLEM IDENTIFICATION

The problem to be addressed is the establishment of a workable framework for the harmonisation of regulatory arrangements between Australia and New Zealand. A treaty between Australia and New Zealand is proposed to set out a workable framework for the Scheme, including the method of establishment of a joint regulatory agency, which meets the needs of both countries

2.3 OBJECTIVES

The objective is to address the problem of establishing a workable framework for the Scheme through a Treaty that puts in place a framework for the Joint Scheme that meets the needs of Australia and is acceptable to New Zealand. The Government was advised of some suggested guiding principles for the Joint Scheme:

- both countries are to have appropriate voice in shaping and modifying the joint regulatory Scheme eg by scrutiny by both Parliaments;
- regulatory decisions are to:
  - be based on parallel legislation in both countries;
  - have effect in both countries; and
  - be enforceable in both countries;
- the Joint Scheme is to have at least the same regulatory coverage as that of the current Australian therapeutic goods legislation;
- there is to be a capacity for both countries to 'opt out' of the joint regulatory arrangements in exceptional circumstances in order to safeguard their sovereignty eg where required by differing cultural factors;

- regulatory decisions are to be made by the regulatory body acting on the advice of experts in relevant fields;
- Australia's existing high regulatory standards and international reputation are to be maintained;
- a joint agency is to be created, in accordance with terms set out in a treaty, as a body corporate under Australian legislation but is to be recognised in New Zealand law so that it can operate in both countries;
- the Joint Agency is to be fully accountable to the Governments and Parliaments of both countries and, in Australia, to the same level as the TGA currently is;
- there is to be direct accountability to the Health Ministers of both countries for the performance of the Agency through a governing body which would oversee the administration of the Agency; and
- there are to be common regulatory review and appeal mechanisms suitable for decisions regarding therapeutic products which will have effect in both countries and which are accessible to industry in both countries.

2.4 REGULATORY OPTIONS

Decisions were made when developing the proposal for the Joint Scheme concerning the most appropriate arrangements to be set out in the Treaty for:

- the establishment and governance of the Joint Agency that will administer the Joint Scheme;
- the accountability of the Agency;
- the legislative basis for the Joint Scheme;
- merits review of Agency decisions; and
- departures from the Joint Scheme.

The proposed arrangements agreed to in these areas are explained below, together with an analysis of their costs and benefits, compared to alternative arrangements.

2.5 ASSESSMENT OF IMPACTS

2.5.1 IMPACT GROUP IDENTIFICATION

The groups likely to be affected by the arrangements are:

- Industry – Australian and New Zealand manufacturers, importers, exporters and suppliers of prescription medicines, over-the-counter medicines, medical devices and complementary medicines;
- Consumers – in Australia and New Zealand
- Government –Australian, State and Territory and New Zealand.

2.5.2 IMPACT ANALYSIS

The Governance of the Agency

Background

The Agency's governance arrangements must ensure that:

- there is direct accountability to the Health Ministers of both countries for the performance of the Agency through a governing body;
- Australia's existing high regulatory standards and international reputation are to be maintained; and
- the joint Agency is fully accountable to the Governments and Parliaments of both countries and, in Australia, to the same level as the TGA.

Problem

How best to achieve governance arrangements for a bi-national organisation that meets the needs of both Australia and New Zealand in relation to the making of regulatory decisions and corporate governance.

Objective

To determine governance arrangements for the Agency that meet the needs of Australia and New Zealand with respect to corporate governance of a bi-national regulatory agency.

Option 1
To set out governance arrangements for the Agency in Australian or New Zealand legislation, or both, and not in the Treaty.

Option 2
To set out the governance arrangements for the Agency in the Treaty.

The governance arrangements outlined in the Treaty can be summarised as follows:

- the establishment under an Australian Act of a trans-Tasman therapeutic products **Agency**, in the manner set out in the Treaty, to administer the Joint **Scheme**;
- the establishment under the Treaty of a **Ministerial Council** comprising the Australian and New Zealand Health Ministers to, among other things, oversee and account to both Parliaments for the Agency and the Joint Scheme, and make Rules to give effect to the Scheme;
- the establishment under the Treaty of a **Board** of five members responsible for the finance and administration of the Agency, and its efficiency, effectiveness and strategic direction, and for reporting to the Ministerial Council about these matters; and

- a **Managing Director** to manage the Agency and perform its regulatory functions (in practice, the Managing Director would delegate the power to make certain decisions to persons with appropriate expertise and/or functional responsibility. Expert advisory committees would be established to provide advice to the decision-maker).

Impacts of Option 1

Benefits

This option does not promote a harmonised approach. Governance arrangements could be changed by the Parliament of the country that is to consider the legislation in a manner that may not be acceptable to the other country.

Costs

If these arrangements were outlined in either Australian or New Zealand legislation, or both, the parliamentary legislative process of either country might change those arrangements so that they are unacceptable to the government of the other country or to stakeholders.

The cost of establishing the governance arrangements will be recovered from industry. Industry is likely to pass this cost on to consumers. The funding costs of this option are likely to be the same as for Option 2.

Impacts of Option 2

Benefits

Outlining these arrangements in the Treaty which is to be formally agreed to by both countries will ensure that they are acceptable to both the Australian and New Zealand governments.

Other stakeholders will benefit from having the roles and responsibilities of the Ministerial Council, the Board and the Managing Director, and their linkages, clearly outlined in a single place (the Treaty) which would not be the case under Option 1 if the governance arrangements were outlined in either the Australian or New Zealand legislation.

Costs

With a treaty, both governments would have to agree to changes and the process of negotiating amendments to a treaty would be slow.

The accountability of the Agency

Background

The financial and administrative accountability arrangements for the Agency should provide for no less accountability to stakeholders than for an Australian Commonwealth authority or a New Zealand Crown entity. Accountability arrangements are needed for matters such as:

- planning and reporting requirements to both Parliaments and Governments;
- the submission of annual reports to the Ministerial Council, including audited financial statements for tabling; and
- audits by the Australian and New Zealand Auditors-General.

Problem

The Agency needs to be accountable to government in a way that is acceptable to both Australia and New Zealand.

Objective

To determine accountability requirements for the Agency that are acceptable to both Australia and New Zealand which are cost-effective and with which the Agency can comply.

Option 1

That the Agency be accountable only to the Australian government or to the New Zealand government.

For example, like FSANZ, the Agency could be accountable to the Australian government under the *Commonwealth Authorities and Companies Act 1997* and the Agency, as part of funding and performance arrangements with New Zealand, contracted to provide specified services to New Zealand in accordance with specified performance measures.

Option 2

The accountability arrangements for the Agency outlined in the Treaty.

The Treaty outlines the following principles for the accountability of the Agency:

- it shall be accountable to Australia and New Zealand for the performance of its functions;
- the level and type of accountability for the Agency is that which would normally apply to a regulatory agency established by the legislation of each country; and

Agreement Between the Government of Australia and the Government of New Zealand for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products done at Wellington on 10 December 2003
[2003] ATNIF 22

Consultations

1. Australian and New Zealand officials have consulted widely with stakeholders on the scope and shape of the joint regulatory scheme that the Treaty provides is to be established. This consultation included the distribution of two consultation papers and numerous meetings with stakeholders. This consultation on the joint Scheme is outlined in detail at pp 21 – 22 of the attached RIS.

2. A significant part of this consultation was the distribution by TGA and Medsafe in June 2002 of a discussion paper entitled A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products, seeking feedback on the design and role of the proposed agency. The paper was distributed in Australia and New Zealand to more than 240 stakeholders and was placed on the TGA and Medsafe web sites for public comment. Letters publicising its release and seeking submissions were sent to all sponsors of therapeutic products on the Australian Register of Therapeutic Goods. Forty written submissions were received from Australian stakeholder groups in response.

3. The discussion paper outlined not only the content of the proposed joint regulatory Scheme but possible methods for establishing the Agency and the Scheme in Australian and New Zealand law. The paper also included an outline of the proposed content of the Treaty.

4. Forty Australian submissions were received in response to that paper, including submissions from Medicines Australia, the Consumer Health Forum, the Australian Self Medication Industry, the Medicines Industry Association of Australia, the Complementary Healthcare Council of Australia, the Pharmaceutical Society of Australia and the Pharmacy Guild, and the Australian Consumer and Specialty Products Association. Only three of the Australian submissions opposed the joint Agency proposal and none provided any substantial comment regarding the proposed content of the Treaty.

5. To ensure the Treaty delivered a workable operational framework for the Scheme and Agency, and that the Agency can meet the legal obligations required of it, consultation was also conducted by the Trans Tasman Group in the TGA with relevant government agencies and experts (particularly legal experts) on the following aspects of the Treaty:

- the method of establishment of the Agency;
- the governance and accountability of the Agency;
- the legislative basis of the joint Scheme;
- how merits and judicial review of Agency decisions is to be conducted; and
- when departures from the joint Scheme may be made.

6. TGA received advice from the following Agencies:

- The Office of General Counsel of the Attorney-General's Department on options for the establishment, structure and governance of the Agency;

- there should be no unnecessary duplication in accountability requirements that apply to the Agency.

The Agency will be fully cost recovered.

The accountability requirements that will apply to the Agency will be set out in Australian or New Zealand legislation, or in the Rules, or in both the legislation and the Rules.

The Treaty specifies that the Agency Board is to provide to the Ministerial Council an annual report on the activities of the Agency and financial statements of the Agency, which will be jointly audited by the Auditors-General of both countries. The Agency will also prepare and provide to the Ministerial Council planning documents, reports, and information as specified in the Rules.

Both Australia and New Zealand may apply to the Agency statutory accountability regimes that apply in the territory of that Party to similar regulatory agencies, but can modify those regimes in a manner consistent with the Treaty, and in particular the accountability principles noted above. The two countries will consult in relation to this.

It is anticipated that the requirements of the *Commonwealth Authorities and Companies Act 1997* (the CAC Act) will be applied to the Agency to the greatest extent possible. Given the joint nature of the Agency and the Scheme there will also be a need for additional accountability requirements to apply to the Agency to accommodate New Zealand's particular needs. It is anticipated, however, that there will be only one set of financial statements to be audited by the Australian and New Zealand Auditors-General.

Impacts of Option 1

Benefits

Option 1 would ensure that there would be no duplication of accountability requirements (eg there would need to be only one audit conducted by a single auditor).

There would therefore be no increased costs due to any duplication of financial statements or auditing.

Costs

As the Agency will be established under Australian law, it is likely, should this approach be adopted, that it would be only the Australian accountability legislation that would apply to the Agency. These costs could be lower than under Option 2.

New Zealand would be expected to have significant concerns with this approach, given the bi-national nature of all other aspects of the Agency, apart from its method of establishment.

Impacts of Option 2

Benefits

Australian industry will be regulated by an Agency subject to the greatest extent possible to the accountability requirements applicable to an Australian government statutory regulatory authority. The planning documents, reports and information to be provided to the Ministerial Council will be publically available and accessible to industry.

The Treaty would ensure that the Agency would be fully accountable to the Governments of both Australia and New Zealand as it would be reporting to the Health Ministers of both countries in relation to its activities and finances. This would enable the Ministerial Council to monitor the Agency's financial operations, and ensure that the Agency performs the activities required of it by both Governments.

It is envisaged that under this option only one set of financial statements would be prepared.

Costs

A key principle of the accountability arrangements for the Agency is that there shall be no unnecessary duplication in accountability (eg reporting) requirements. The circumstances in which there would need to be duplication, given the novel nature of the need for the Agency to report to two Governments, are still being finalised. It is unlikely that there will be a significant increase in the reporting requirements for industry.

There will be some additional costs to government to establish the new accountability requirements, just as there will be costs involved in establishing other aspects of the Agency arrangements.

The legislative arrangements for the Joint Scheme

Background

Australia and New Zealand need to agree to a legislative framework for the Joint Scheme by outlining in the Treaty the framework that will be used.

Problem

The legislative framework needs to meet the following applicable key parameters for the Joint Scheme:

- both countries are to have appropriate voice in shaping and modifying the joint regulatory Scheme eg by scrutiny by both Parliaments;
- regulatory decisions are to:
  - be based on parallel legislation in both countries;

- have effect in both countries; and
- be enforceable in both countries; and

- the Agency is to be fully accountable to the Governments and Parliaments of both countries.

Objective

To determine a workable legislative framework for the Joint Scheme that meets the needs of both Australia and New Zealand.

Option 1

Continued separate legislative arrangements in Australia and New Zealand
ie separate Acts and regulations, with possibly a single set of Orders made by the Managing Director of the Agency to be referenced in both Acts or regulations.

Option 2

The legislative arrangements for the Joint Scheme outlined in the Treaty.

The Treaty provides that the Joint Scheme will be set out in three forms of legislation:

Acts of the Australian and New Zealand Parliaments – to be drafted in the same terms as much as possible;

Rules – to be made by the Ministerial Council before being tabled in both the Australian and New Zealand Parliaments, to be disallowable by either Parliament and, if disallowed by a Parliament, to be of no effect in either Australia or New Zealand; and,

Orders – to be made by the Managing Director, but in other respects to be subject to the same tabling and disallowance requirements as Rules.

The **Rules** made by the MC would contain the details of pre-market application procedures for the major product groups to be regulated – prescription medicines, over-the-counter medicines, complementary medicines and medical devices and other therapeutic products including some sunscreens and blood and blood components. They would also include other components of the regulatory process such as good manufacturing practice (GMP) requirements, product licences, scheduling, advertising, import and export requirements, and fees and charges. The Rules would also set out the details of the expert advisory committees and accountability requirements.

Orders made by the MD would include items such as product quality and safety standards, lists of exempted goods, GMP details, labelling and advertising requirements and lists of substances permitted for use in low-risk medicines.

Australia and New Zealand would commit under the Treaty to legislate to provide that Rules can only be disallowed within a reasonable time from tabling, that they can be disallowed only in whole (and not in part) and that Rules and Orders commence either when they are published (shortly after they are made by the Ministerial Council), or on any date specified in the Rules, whichever is the later date.

The two countries have also agreed that the effect of any disallowance will be prospective only. This arrangement will be reflected in the Rules.

Under this option, a balance will need to be struck between matters to be located in the Acts and matters to be located in the Rules and Orders. For example, substantial offences will need to be in the primary legislation while the bulk of the regulatory requirements will be in the single set of Rules.

Impacts of Option 1

Benefits

There would be no perceived loss of sovereignty to either Australia or New Zealand under Option 1 as neither Government would have to agree that regulatory requirements in a disallowable instrument with which it is satisfied, but with which the other Government is not satisfied, will cease to have effect if that instrument is disallowed by the other country.

There would appear to be no other benefits to industry, consumers or government.

Costs

Separate legislative arrangements could lead to loss of uniformity of requirements resulting in added costs to business in order to comply with two sets of differing requirements eg for product registration and labelling.

Impact of Option 2

Benefits

The arrangements for legislation outlined in the Treaty providethe best chance of establishing truly harmonised regulatory arrangements. Industry need comply with only one set of requirements in both Australia and New Zealand.

Costs

The option would be more costly to the government of the country which assumes primary carriage for drafting the implementing legislation though both countries would have to commit resources to the negotiation and consultation processes. These costs would not be recovered from industry.

There may also be a perceived loss of sovereignty to both Australia andd New Zealand under this Option as both Governments would need to agree that regulatory requirements with which it is satisfied, but the other government is not, will cease to have effect if disallowed by the other country.

Merits review of Agency decisions

Background

Principal regulatory decisions under the *Therapeutic Goods Act 1989* are currently reviewable by the Administrative Appeals Tribunal (AAT) following a statutory internal review process. In New Zealand, an appeal against a licensing decision under the *Medicines Act 1981* is heard by the Medicines Review Committee appointed under that Act. The Medicines Review Committee may confirm, reverse, or modify a licensing decision.

The frequency of cases in Australia is small and there has been none in New Zealand for more than five years, where challenges to decisions are reportedly settled within an informal process of internal review.

New Zealand does not have a centralised administrative review framework equivalent to the Commonwealth AAT system but has a system that is more ad hoc in nature. New Zealand has established individual tribunals to review particular legislation, such as the Human Rights Review Tribunal, the Medical Practitioners Disciplinary Tribunal, and Trans Tasman Occupations Tribunal. The Department of Courts services these bodies.

Problem

The Joint Scheme must provide Australian and New Zealand stakeholders with a right to merits review of the regulatory decisions of the Agency that is acceptable to both Australia and New Zealand.

Objective

To determine a cost-effective mechanism for independent, impartial and transparent merits review of Agency decisions by an appropriately qualified review body in accordance with the rules of procedural fairness, which will result in decisions that will apply in both Australia and New Zealand.

Option 1

A new bi-national trans-Tasman merits review body.

Under this option, there would be a single standing body with membership appointed by the Ministerial Council that would have an appropriate range of expertise, including a

convenor. The convenor would convene a suitably qualified review panel from the membership of the standing body whenever a review was required, and each review panel would operate in accordance with procedures set out in the Ministerial Council Rules.

There would be no diminution of the rights currently available to applicants for review of decisions by the AAT in relation to therapeutic goods. Equivalent decisions under the new Scheme would be reviewable by the bi-national trans-Tasman merits review body. Mandatory internal review of Agency decisions would be provided for before external merits review.

The procedure for reviews (and thus the form of procedural fairness to be afforded to applicants by such a bi-national review body) and membership of the standing body would need to be agreed by Australia and New Zealand.

Regulatory decisions of the Agency would be given effect under Australian and New Zealand legislation. If such regulatory decisions are reviewed, the decision of the bi-national merits review body would be similarly given effect in place of the original decision.

Option 2

Merits review of regulatory decisions by the Agency as outlined in the Treaty.

Australia and New Zealand would legislate to provide for review of regulatory decisions made by the Agency by separate Review Tribunals in each country with panels drawn from a common pool of members. The Australian Review Tribunal would be the AAT, with potentially some additional members with expertise in relevant areas. New Zealand would need to set up a new Review Tribunal.

There would be no diminution of the rights currently available to applicants for review of decisions by the AAT in relation to therapeutic products. Equivalent decisions under the new Scheme would continue to be reviewable by the AAT as it will be the Australian Review Tribunal under this proposal.

There would be a Principal Member for each Review Tribunal. It is proposed that the Principal Member nominated for Australia will be the President of the AAT. The common pool of members of the two Tribunals (known as the "Merits Review Panel") would be established and maintained by the Ministerial Council.

In Australia, the rules of procedure for the AAT that are set out in the *Administrative Appeals Tribunal Act 1975* (and thus the form of procedural fairness to be afforded to applicants) would apply to the Australian Review Tribunal. The rules of procedure for the New Zealand Review Tribunal are expected to be based upon the AAT rules of procedure. New Zealand officials have advised that they are broadly comfortable with adopting much of the procedural requirements from the AAT system.

There will be a capacity to also set out procedural requirements for the two Tribunals in the Ministerial Council Rules. It is envisaged that these would comprise any modifications to the usual procedures that are necessary to take into account the joint nature of the Scheme and enable the two Tribunals to work together cooperatively.

Internal review of Agency regulatory decisions would be mandatory before external merits review. Regulatory decisions of the Agency would be given effect under Australian and New Zealand legislation. If such regulatory decisions are reviewed, the decision of the Review Tribunal conducting the review would be similarly given effect in place of the original decision.

Impacts of Option 1

Benefits

A specialised bi-national review body would have members chosen specifically for their expertise in areas relevant to review of the types of specialised decisions made by the Agency. It would also avoid divergency of approach to decisions that might flow from the establishment of two tribunals proposed in Option 2.

Costs

The costs to government in establishing and maintaining a bi-national body are hard to determine but would probably be significant. Establishing an international tribunal is a difficult task and involves some sensitivities on issues of sovereignty.

There would be costs involved in determining the functions of the new body and its procedural rules, developing and implementing an administrative infrastructure for the new body, and appointing and remunerating both members of the body and administrative support staff. All these matters would also involve significant negotiation with New Zealand.

All stakeholders would incur costs relating to familiarising themselves with the new procedural requirements of a new a body.

Impacts of Option 2

Benefits

Australian stakeholders are familiar with the operation of the merits review scheme proposed by Option 2, as the existing AAT system would be used for the conduct of merits reviews in Australia. They would also be assured of the continued protection afforded by the principles of procedural fairness that underpin the conduct of reviews by the AAT. For example, parties will be able to appeal to the Federal Court from decisions of the Review Tribunal on questions of law (eg on the grounds of bias, or lack of a fair hearing), just as they can at present in relation to AAT decisions.

It is expected that review applicants in Australia would continue to pay the fees applicable under the AAT fee structure.

All stakeholders would benefit from merits review of Agency regulatory decisions by reviewers drawn from a common pool of reviewers with expertise in medicine, therapeutic products, public administration or law - expertise specifically relevant to the review of the types of specialised decisions to be made by the Agency. Stakeholders would also benefit from the experience of the AAT in conducting general merits review.

Government will benefit from maintaining a consistent approach to merits review in Australia by retaining the AAT as the review tribunal for Australia of decisions relating to therapeutic products.

Costs

As the AAT will continue to conduct merits review of regulatory decisions concerning therapeutic products in Australia, there should be no additional cost to the Australian government, other than possible costs relating to the appointment of any additional members of the Merits Review Panel who are not already on the AAT. The appointment of such additional members would, however, need to be approved in accordance with the legislative requirements for appointment to the AAT by the Governor-General.

Departures from the Joint Scheme

Background

The Joint Scheme will achieve the objectives of the TTMRA in relation to therapeutic products as it will harmonise Australia and New Zealand's regulatory arrangements for the great majority of therapeutic products. However, there will still be a need for arrangements within the Treaty for departures by either Australia or New Zealand from the harmonised Scheme in exceptional circumstances.

Problem

Australia and New Zealand must retain the right to unilaterally regulate specified therapeutic products where, in exceptional cases, either government considers this necessary. On the other hand, the actioning of this right should not undermine the efficient operation of the Joint Scheme itself and the benefits that will flow from the harmonised regulation by the two countries of therapeutic products.

Objective

To enable timely and administratively effective departures from the joint regulatory Scheme in relation to specified therapeutic products that will not undermine the operation of the Joint Scheme and which is acceptable to both Australia and New Zealand.

Option 1

Departures from the Joint Scheme to be made in accordance with the arrangements under the *Trans-Tasman Mutual Recognition Arrangement* for exemptions from the operation of that Arrangement.

This would mean that short term departures from the Joint Scheme for a specified therapeutic product or class of therapeutic product would be available by means of a temporary exemption unilaterally invoked by either jurisdiction on the grounds available under the TTMRA (a threat to health, safety or the environment) by means of a regulation. Such a departure could be extended up to twelve months with the agreement of two thirds of the Australian jurisdictions and NZ when the Australian Health Ministers and the New Zealand Health Minister decide upon the future of the exemption. Permanent exemptions for such products would also be available with the agreement of not less than two thirds of all jurisdictions.

Option 2

The arrangements for departures from the Joint Scheme that are set out in the Treaty.

Under these arrangements, both Australia and New Zealand could opt out from the joint regulatory arrangements in exceptional circumstances by means of regulations. The application of the Joint Scheme in respect of a therapeutic product, or class of therapeutic product, could be excluded or modified by legislative action. However, this could only be done by either country if it is satisfied that it is necessary for it to do so having regard to exceptional public health, safety, third country trade, environmental or cultural factors that affect the party.

The Treaty ensures that the other country can comment on a proposed departure before it occurs, that the Party that made the departure is to keep it under review and consult on the continuing need for it at the request of the other Party, that the Ministerial Council annually review any departures, and make recommendations in relation to them to the two countries where necessary.

It is expected that these arrangements will need some form of exemption from the operation of the TTMRA to ensure that products which are no longer regulated under the Joint Scheme, or to which a modification of the Scheme applies, cannot be imported into the country that has not departed from the Scheme. The States and Territories have been advised of the arrangements proposed in the Treaty and the need for some form of exemption from the TTMRA for them to operate.

Impacts of Option 1

Benefits

Some stakeholders may see a benefit in any departures from the Joint Scheme in relation to particular products or classes of therapeutic products being able to be made only on the grounds available for departure under the TTMRA. These opt out arrangements would maintain the sovereignty of both countries. Parliament would also have the capacity to scrutinise any departures from the Joint Scheme.

Costs

Following the TTMTRA process involves resources costs in consulting the States and Territories.

Impacts of Option 2

Benefits

Departures under these arrangements would be less time consuming and easier to implement administratively than departures under the TTMRA system. They would provide the joint Agency with the ability to deal with exceptional circumstances in a timely and administratively effective manner.

These arrangements assure consumers that therapeutic products can still be unilaterally regulated by their own country to take into consideration any health, safety, environmental or cultural matters specific to that country in the highly unlikely situation where that country considers that such matters have not been adequately taken into consideration by the Joint Scheme.

The opt out arrangements in the Treaty also maintain the sovereignty of both countries. Parliament would also have the capacity to scrutinise any departures from the Joint Scheme as departures would be actioned by means of regulations.

Costs

No additional costs, unless the regulatory arrangements put in place by the country departing from the Scheme to replace the joint regulatory arrangements impose additional costs. Any additional costs of such alternative arrangements would of course depend upon the nature of those arrangements.

2.6. CONSULTATION

In June 2002, Medsafe and TGA distributed joint discussion documents, seeking feedback on the design and role of the proposed agency. A discussion paper entitled A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products was distributed in June 2002 in both Australia and New Zealand. The discussion paper outlined not only the content of the proposed joint regulatory Scheme but possible methods for establishing the Agency and the Scheme in Australian and New Zealand law. The paper included an outline of the proposed content of the Treaty.

Forty Australian submissions were received in response to that paper, including submissions from Medicines Australia, the Consumer Health Forum, the Australian Self Medication Industry, the Medicines Industry Association of Australia, the Complementary Healthcare Council of Australia, the Pharmaceutical Society of Australia and the Pharmacy Guild, and the Australian Consumer and Specialty Products Association. Only three of the Australian submissions opposed the joint Agency proposal and none provided any substantial comment regarding the proposed content of the Treaty.

States and Territories have been provided with a copy of the proposed Treaty through the Standing Committee on Treaties and have provided comments.

The only significant area of concern raised by jurisdictions has been the potential for the Australian Government to use the external affairs power under the Treaty to eliminate the State and Territory role in the scheduling of drugs and poison scheduling. The Government has assured the States and Territories that it has no intention to vary the current role of States and Territories in regulating access to, or the availability of, scheduled drugs and poisons.

Industry is aware that the Agency will fully recover the costs of its activities under the Joint Scheme. Consultation with industry and consumers on the specific amount of fees and charges will occur in 2004-05 prior to the Agency commencing operation.

Consultation conducted prior to June 2002 is described above under the heading *Consultation* in Part 1 of this RIS.

2.7 CONCLUSION AND RECOMMENDED OPTION

That Option 2 for all the key aspects of the Joint Scheme be adopted.

2.8 IMPLEMENTATION AND REVIEW

Exposure drafts of the two Implementing Acts will be released for public comment together with an explanatory document providing details of the proposed Scheme. Consultation will occur on the Rules as they are developed.

Officials from Australia and New Zealand are working on the development of transitional arrangements necessary to achieve the smoothest possible transition to the new legislation underpinning the Joint Scheme established by the Treaty. These transitional arrangements will cover both the regulatory requirements (eg expansion of TGA's current list of substances approved for inclusion in low-risk complementary medicines, to assist New Zealand complementary medicines to qualify for a self-assessed product licence); and administrative arrangements. A new IT data and information base will be developed to support the range of regulatory processes in both countries.

The Treaty provides for a review by Australia and New Zealand of the effectiveness of the Scheme and of the Agency, with a view to agreeing to and implementing any necessary improvements, no later than five years from the entry into force of the Treaty.

NEW ZEALAND POLITICAL BRIEF

1. Australia and New Zealand share a special relationship as neighbours and close economic partners, with unique inter-governmental structures, historic, cultural and people-to-people links. But we remain two sovereign nations with distinct national interests.

2. New Zealand is Australia's most important ally in the South Pacific and an important partner beyond. Over many decades, New Zealand has made valuable contributions in areas of high priority to Australia, most recently in East Timor, Bougainville and Solomon Islands and in responding to people smuggling.

3. The Australia New Zealand Closer Economic Agreement (ANZCERTA, or CER) was signed in 1983. CER is one of the most successful examples of economic integration in the world and a model for others. CER and the web of arrangements and agreements which support it provide a seamless business environment through a common approach to many standards and regulatory issues.

4. An ambitious program of economic integration will continue, through increased regulatory coordination, harmonisation of customs and business laws, closer alignment of securities systems and further work on taxation. There are nonetheless political, economic and practical limits to further integration.

5. The flows of people across the Tasman are substantial. Neither Australia nor New Zealand wants to put at risk the entitlement of our citizens under the Trans-Tasman Travel Arrangement to free movement, residence and work in each other's country. Both countries have a common responsibility, however, to protect the integrity of our borders and immigration processes.

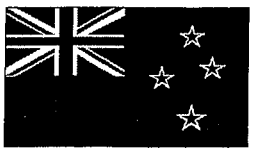
6. Australia continues to work closely with New Zealand on defence issues and encourages the New Zealand Government to see defence as an important tool of strategic diplomacy, even though our strategic visions and proportions of defence spending differ considerably.

7. The trans-Tasman relationship will necessarily evolve as differences in economic strength, political systems, ethnic composition and strategic outlook become more apparent. Australia has a strong and direct interest in a dynamic relationship with an outward-looking and economically strong New Zealand.

- International law experts from the Department of Foreign Affairs and Trade and Attorney-General's Office of International Law, on establishing the agency in a way that did not create an international organisation;
- Office of Parliamentary Counsel, on the best way to establish the agency in legislation and provide it with legal personality;
- The Australian Government Solicitor's commercial practice, on Agency governance and control;
- Phillips Fox's Professor Dennis Pearce, on administrative law issues including judicial review;
- Department of Finance and Administration's Legislative Review Branch, on structure and accountability;
- The Administrative Review Council, Attorney-General's Civil Justice Division and Prime Minister and Cabinet's Governance Division on administrative law issues, and on merits review in particular.

7. Three face to face meetings between Australian and New Zealand officials were conducted in 2003 to develop the treaty text. Teleconferences to finalise particular parts of the text were also held. Officials from relevant Australian and New Zealand government agencies attended these negotiations as required. For Australia, officials from the Australian Department of Foreign Affairs and Trade, the Department of Prime Minister and Cabinet, the Therapeutic Goods Administration of the Department of Health and Ageing, the Attorney-General's Department, the Australian Government Solicitor and the Department of Industry, Tourism and Resources attended and provided advice within their fields of expertise as required.

8. States and Territories were provided with a copy of the proposed Treaty through the Standing Committee on Treaties and also provided comments (see p 5 of this NIA).



NEW ZEALAND

Fact Sheet

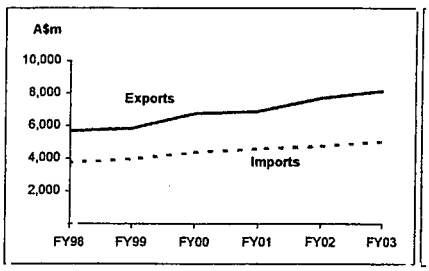
General information:

Capital:	Wellington	**Head of State:**	
Surface area:	271 thousand sq km	H.M. Queen Elizabeth II, represented by Governor-	
Official language:	English	General The Rt Hon Dame Silvia Cartwright	
Population:	3.9 million (2002)	**Head of Government:**	
Exchange rate:	A$1 = NZ$ 1.1403 (Nov 2003)	Prime Minister The Rt Hon Helen Clark MP	

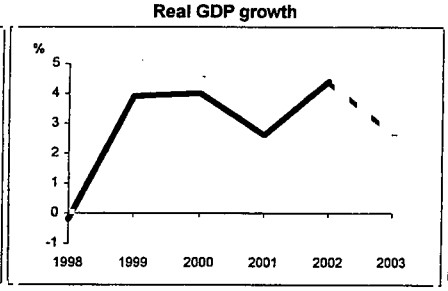
Recent economic indicators:

	1998	1999	2000	2001	2002(a)	*2003(b)*
GDP (US$bn) (c):	54.2	56.0	51.4	50.5	58.2	*73.4*
GDP per capita (US$):	14,304	14,612	13,296	12,936	14,804	*18,497*
Real GDP growth (% change YOY):	-0.2	3.9	4.0	2.6	4.4	*2.6*
Current account balance (US$m):	-2,166	-3,519	-2,457	-1,312	-2,151	*-2,746*
Current account balance (% GDP):	-4.0	-6.3	-4.8	-2.6	-3.7	*-3.7*
Goods & services exports (% GDP):	29.6	30.5	35.2	36.3	33.8	*29.2*
Inflation (% change YOY):	1.6	1.1	2.7	2.7	2.7	*2.0*
Unemployment rate (%):	7.5	6.8	6.0	5.3	5.2	*5.4*

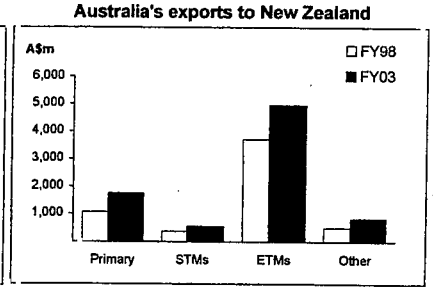
Australia's trade with New Zealand



Real GDP growth



Australia's exports to New Zealand



Australia's trade relationship with New Zealand:

Major Australian exports, 2002-2003 (A$m):		**Major Australian imports, 2002-2003 (A$m):**	
Petroleum and petroleum products	705	Paper and paperboard	316
Office machines and equipment	526	Crude petroleum	313
Passenger motor vehicles	526	Electrical machinery and appliances	296
Paper and paperboard	347	Wood, simply worked	258
Medicinal and pharmaceutical products	342	Non-monetary gold	190

Australian merchandise trade with New Zealand, 2002-2003:		***Total share:***	***Rank:***	***Growth (yoy):***
Exports to New Zealand (A$m):	8,120	7.0%	5th	6.0%
Imports from New Zealand (A$m):	5,019	3.8%	6th	5.9%
Total trade (exports + imports) (A$m):	13,139	5.3%	5th	5.9%
Merchandise trade surplus with New Zealand (A$m):	3,101			

Australia's trade in services with New Zealand, 2002-2003:		***Total share:***
Exports of services to New Zealand (A$m):	2,339	7.2%
Imports of services from New Zealand (A$m):	1,809	5.5%
Services trade surplus with New Zealand (A$m):	530	

New Zealand's global trade relationships:

New Zealand's principal export destinations, 2002:			**New Zealand's principal import sources, 2002:**		
1	*Australia*	*18.9%*	*1*	*Australia*	*22.7%*
2	United States	15.5%	2	United States	13.5%
3	Japan	11.9%	3	Japan	12.0%
4	United Kingdom	4.9%	4	China	8.0%
5	China	4.8%	5	Germany	5.1%

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; (c): Year beginning April 1st.

Fact sheets are updated biannually; next update: May 2004

Treaties between Australia and New Zealand

- Australia-New Zealand Agreement [ANZAC Pact]
  [1944] ATS 02

- Australia New Zealand Closer Economic Relations Trade Agreement [ANZCERTA]
  [1983] ATS 02

- Exchange of Letters constituting an Agreement concerning the Supply of Phosphate from Christmas Island
  [1983] ATS 26

- Agreement to provide for the Termination of the Christmas Island Agreement of 1958-81
  [1983] ATS 29

- Agreement on Seismic Monitoring Cooperation
  [1987] ATS 10

- Protocol on Harmonisation of Quarantine Administrative Procedures to ANZCERTA of 28 March 1983
  [1988] ATS 17

- Protocol on Acceleration of Free Trade in Goods to ANZCERTA of 28 March 1983
  [1988] ATS 18

- Protocol on Harmonisation of Quarantine Administrative Procedures to ANZCERTA of 28 March 1983
  [1988] ATS 20

- Exchange of Letters to amend to ANZCERTA of 28 March 1983
  [1988] ATS 27

- Agreement for the Reciprocal Protection of Classified Information of Defence Interest
  [1989] ATS 03

- Agreement concerning the Collaboration in the Acquisition of Surface Combatants for the Royal Australian Navy and the Royal New Zealand Navy [ANZAC Frigates Agreement]
  [1989] ATS 32

- Agreement concerning Cooperation in Defence Logistics Support
  [1991] ATS 14

- Exchange of Letters constituting an Agreement to delete Article 20.3 and Annex F from ANZCERTA of 28 March 1983
  [1992] ATS 27

- Exchange of Letters constituting an Agreement relating to Nauru
  [1994] ATS 17

- Exchange of Letters constituting an Agreement to amend Article 3.1 of ANZCERTA of 28 March 1983
  [1994] ATS 39

- Agreement Establishing a System for Joint Food Standards
  [1996] ATS 12

- Agreement for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income
  [1997] ATS 23

- Exchange of Letters constituting an Agreement to amend the ANZAC Frigates Agreement of 14 December 1989
  [1997] ATS 24

- Agreement concerning the Establishment of the Governing Board, Technical Advisory Council and Accreditation Review Board of the Joint Accreditation System of Australia and New Zealand [JAS-ANZ II]
  [1998] ATS 16

- Agreement on Medical Treatment for Temporary Visitors with New Zealand
  [1999] ATS 15

- Agreement concerning the Transfer of Uranium
  [2000] ATS 16

- Agreement on Child and Spousal Maintenance
  [2000] ATS 20

- Agreement on Social Security
  [2002] ATS 12

- Exchange of Notes Amending the Agreement on Social Security of 28 March 2001
  [2002] ATS 12

- Agreement concerning a Joint Food Standards System
  [2002] ATS 13

- Agreement relating to Air Services
  [2003] ATS 18

- Agreement concerning the Status of Forces
  [1998] ATNIF 14

- Agreement for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products
  [2003] ATNIF 22

- Exchange of Letters constituting an Agreement to amend Article 3 of ANZCERTA of 28 March 1983
  [2004] ATNIF 01

There are no treaties of the same type with any other country.