Australian Treaty Series (not yet in force)

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.

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;

(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 Annette King

Parliamentary Secretary for Minister for Health

The Minister for Health and Ageing

FOR THE GOVERNMENT OF FOR THE GOVERNMENT OF

AUSTRALIA 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.