AGREEMENT

between the European Union and New Zealand amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and New Zealand

THE EUROPEAN UNION

and

NEW ZEALAND,

hereinafter 'the Parties',

HAVING concluded the Agreement on mutual recognition in relation to conformity assessment [1], done at Wellington on 25 June 1998 (hereinafter 'the Agreement on Mutual Recognition');

NOTING the need to simplify the operation of the Agreement on Mutual Recognition;

WHEREAS Article 3 of the Agreement on Mutual Recognition sets out the form of the Sectoral Annexes in detail, and, specifically, provides that Section II of each Sectoral Annex to the Agreement shall contain a list of the designated conformity assessment bodies;

WHEREAS Article 4 of the Agreement on Mutual Recognition restricts the application of the Agreement to products that originate in the Parties according to non-preferential rules of origin;

WHEREAS Article 12 of the Agreement on Mutual Recognition establishes a Joint Committee that, inter alia, gives effect to decisions on the inclusion of conformity assessment bodies in, and their removal from, the Sectoral Annexes and sets out a procedure for such inclusion and removal;

WHEREAS Articles 8 and 12 of the Agreement on Mutual Recognition refer to the Chair of the Joint Committee;

WHEREAS Article 12 of the Agreement on Mutual Recognition does not explicitly empower the Joint Committee to amend the Sectoral Annexes, except to give effect to the decision by a designating authority to designate or to withdraw designation of a particular conformity assessment body;

CONSIDERING that Article 3 of the Agreement on Mutual Recognition should be amended, both to reflect the changes proposed to Article 12 thereof to limit the requirement for the Joint Committee to take action on the recognition or withdrawal of recognition of conformity assessment bodies to cases that have been contested by the other Party under Article 8 of the Agreement on Mutual Recognition, and to allow greater flexibility in the structure of Sectoral Annexes to the Agreement;

CONSIDERING that in order that trade between the Parties is not unnecessarily restricted, the origin restriction in Article 4 of the Agreement on Mutual Recognition should be deleted;

CONSIDERING that in order to reflect the fact that the Joint Committee is co-chaired by the Parties, the references to the Chair of the Joint Committee should be deleted from Articles 8 and 12 of the Agreement on Mutual Recognition;

CONSIDERING that enhanced exchange of information between the Parties regarding the operation of the Agreement on Mutual Recognition will facilitate its operation;

CONSIDERING that in order to make timely adaptations to the Sectoral Annexes so as to take account of technical progress, and other factors such as enlargement of the European Union, the Joint Committee should be explicitly empowered in Article 12 of the Agreement on Mutual Recognition to amend the Sectoral Annexes in areas other than to give effect to the decision by a designating authority to designate or to withdraw designation of a particular conformity assessment body, and also to adopt new Sectoral Annexes;

[1] OJ L 229, 17.8.1998, p. 62.

CONSIDERING that in order to simplify the operation of the Agreement on Mutual Recognition, the need for the Joint Committee to take decisions on the recognition or withdrawal of recognition of conformity assessment bodies should be limited to cases that have been contested by the other Party under Article 8 of the Agreement on Mutual Recognition;

CONSIDERING that in order to simplify the operation of the Agreement on Mutual Recognition, a simpler procedure for the recognition, withdrawal of recognition, and suspension of conformity assessment bodies should be set up in Article 12 thereof, and the position regarding conformity assessment carried out by bodies before their designation is suspended or withdrawn should be clarified;

CONSIDERING that the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia is identical in form to the Agreement on Mutual Recognition, and is therefore being amended in parallel in order to retain coherence between the Agreements;

CONSIDERING that the legal references and mode of operation of the Sectoral Annexes on medicinal products GMP inspection and batch certification and on medical devices are outdated, and the opportunity has been taken to amend them to reflect the current position,

HAVE AGREED AS FOLLOWS:

Article 1

Amendments to the Agreement on Mutual Recognition

The Agreement on Mutual Recognition is hereby amended as follows:

1. Article 3(2) is replaced by the following:

'2. Each Sectoral Annex shall, in general, contain the following information:

(a) a statement of its scope and coverage;

(b) the legislative, regulatory and administrative requirements pertaining to the conformity assessment procedures;

(c) the designating authorities;

(d) a set of procedures for the designation of conformity assessment bodies, and

(e) additional provisions as required.'.

2. Article 4 is replaced by the following:

'*Article 4*

Scope and coverage

This Agreement shall apply to products specified in the statement of scope and coverage in each Sectoral Annex.'.

3. Article 6 is replaced by the following:

'*Article 6*

Designating authorities

1. The Parties shall ensure that the designating authorities responsible for designating conformity assessment bodies have the necessary power and competence to designate, suspend, remove suspension and withdraw the designation of such bodies.

2. In making such designations, suspensions, removals of suspension and withdrawals, designating authorities shall, unless specified otherwise in the Sectoral Annexes, observe the procedures for designation set out in Article 12 and the Annex.'.

4. Article 7(1) is replaced by the following:

'1. The Parties shall exchange information concerning the procedures used to ensure that the designated conformity assessment bodies under their responsibility comply with the legislative, regulatory and administrative requirements outlined in the Sectoral Annexes and the competence requirements specified in the Annex.'.

5. Article 8 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. Such contestation has to be justified in an objective and argued manner and in writing to the other Party and to the Joint Committee.';

(b) paragraph 6 is replaced by the following:

'6. Except when decided otherwise by the Joint Committee, the contested conformity assessment body shall be suspended by the competent designating authority from the time its technical competence and compliance is contested in accordance with this Article until either agreement is reached in the Joint Committee on the status of that body or the challenging Party notifies the other Party and the Joint Committee that it is satisfied as to the technical competence and compliance of that body.'.

6. Article 9 is replaced by the following:

'Article 9

Exchange of information

1. The Parties shall exchange information concerning the implementation of the legislative, regulatory and administrative provisions identified in the Sectoral Annexes and shall maintain an accurate list of conformity assessment bodies designated in accordance with this Agreement.

2. Consistent with their obligations under the World Trade Organization Agreement on Technical Barriers to Trade, each Party shall inform the other Party of the changes it intends to make to the legislative, regulatory and administrative provisions relating to the subject matter of this Agreement and shall, except as provided for in paragraph 3 of this Article, notify the other Party of the new provisions at least 60 calendar days before their entry into force.

3. Where a Party takes urgent measures that it considers warranted by considerations of safety, health or protection of the environment in order to manage a risk posed by a product covered by a Sectoral Annex, it shall notify immediately the other Party of the measures, with a brief indication of their objective and rationale, or as otherwise specified in the Sectoral Annex.'.

7. Paragraphs 3 to 7 of Article 12 are replaced by the following:

'3. The Joint Committee shall meet at least once a year unless the Joint Committee or the Parties decide otherwise. If required for the effective functioning of this Agreement, or at the request of either Party, an additional meeting or meetings shall be held.

4. The Joint Committee may consider any matter related to the functioning of this Agreement. In particular, it shall be responsible for:

(a) amending the Sectoral Annexes in accordance with this Agreement;

(b) exchanging information concerning the procedures used by either Party to ensure that the conformity assessment bodies maintain the necessary level of competence;

(c) in accordance with Article 8, appointing a joint team or teams of experts to verify the technical competence of a conformity assessment body and its compliance with other relevant requirements;

(d) exchanging information and notifying the Parties of modifications of legislative, regulatory and administrative provisions referred to in the Sectoral Annexes including those which require modification of the Sectoral Annexes;

(e) resolving any questions relating to the application of this Agreement and its Sectoral Annexes, and

(f) adopting new Sectoral Annexes in accordance with this Agreement.

5. Any amendments to the Sectoral Annexes made in accordance with this Agreement and any new Sectoral Annexes adopted in accordance with this Agreement shall be notified promptly in writing by the Joint Committee to each Party, and shall come into effect as determined by the Joint Committee.

6. The following procedure shall apply in relation to the designation of a conformity assessment body:

(a) a Party wishing to designate a conformity assessment body shall forward its proposal to that effect to the other Party in writing, adding supporting documentation, as may be defined by the Joint Committee;

(b) in the event that the other Party consents to the proposal or upon the expiry of 60 calendar days without an objection having been lodged, in accordance with any applicable procedures established by the Joint Committee, the conformity assessment body shall be considered to be a designated conformity assessment body under the terms of Article 5;

(c) in the event that, under Article 8, the other Party contests the technical competence or compliance of the proposed conformity assessment body within the aforementioned 60-day period, the Joint Committee may decide to carry out a verification of the body concerned, in accordance with Article 8;

(d) in the case of the designation of a new conformity assessment body, conformity assessment carried out by such a body shall be valid from the date on which it becomes a designated conformity assessment body in accordance with this Agreement;

(e) either Party may suspend, remove the suspension of, or withdraw the designation of a conformity assessment body under its jurisdiction. The Party concerned shall immediately notify the other Party and the Joint Committee of its decision in writing, together with the date of such decision. The suspension, removal of suspension or withdrawal of the designation shall take effect from the date of the Party's decision;

(f) in accordance with Article 8, either Party may, in exceptional circumstances, contest the technical competence of a designated conformity assessment body under the jurisdiction of the other Party. In this case the Joint Committee may decide to carry out a verification of the body concerned, in accordance with Article 8.

7. In the event that the designation of a conformity assessment body is suspended or withdrawn, conformity assessment carried out by that body before the date of effect of the suspension or withdrawal shall remain valid unless either the responsible Party has limited or cancelled that validity, or the Joint Committee determines otherwise. The Party under whose jurisdiction the suspended or withdrawn conformity assessment body was operating shall notify the other Party in writing of any such changes relating to a limitation or cancellation of validity.'.

8. Article 15 is amended as follows:

(a) paragraph 3 is replaced by the following:

'3. The Joint Committee may adopt Sectoral Annexes to which Article 2 applies and which will provide the implementing arrangements for this Agreement.';

(b) paragraph 4 is replaced by the following:

'4. Amendments to the Sectoral Annexes, and the adoption of new Sectoral Annexes, shall be determined by the Joint Committee.'.

9. The Annex is hereby amended as follows:

(a) paragraph 9 is replaced by the following:

'9. Designating authorities shall inform their Party's representatives on the Joint Committee, established under Article 12 of this Agreement, of the conformity assessment bodies to be designated, suspended or withdrawn. The designation, suspension or withdrawal of designation of conformity assessment bodies shall take place in accordance with this Agreement and the rules of procedure of the Joint Committee.';

(b) paragraph 10 is replaced by the following:

'10. When advising their Party's representative on the Joint Committee established under this Agreement, of the conformity assessment bodies to be designated, the designating authority shall provide the following details in respect of each conformity assessment body:

(a) the name;

(b) the postal address;

(c) the facsimile (fax) number and e-mail address;

(d) the range of products, processes, standards or services it is authorised to assess;

(e) the conformity assessment procedures it is authorised to carry out; and

(f) the designation procedure used to determine competence.'.

10. The Sectoral Annex on medicinal products GMP inspection and batch certification, including Appendix 1 and Appendix 2, is replaced by the following:

'**SECTORAL ANNEX ON MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION TO THE EUROPEAN COMMUNITY – NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT**

SCOPE AND COVERAGE

1. The provisions of this Sectoral Annex cover all medicinal products which are industrially manufactured in New Zealand and in the European Union, and to which Good Manufacturing Practice (GMP) requirements apply.

For medicinal products covered by this Sectoral Annex, each Party will recognise the conclusions of inspections of manufacturers carried out by the relevant inspection services of the other Party and the relevant manufacturing authorisations granted by the competent authorities of the other Party.

In addition, the manufacturer's certification of the conformity of each batch to its specifications will be recognised by the other Party without re-control at import.

'Medicinal products' means all products regulated by the pharmaceutical legislation in the European Union and New Zealand referred to in Section I. The definition of medicinal products includes all human and veterinary products, such as chemical and biological pharmaceuticals, immunologicals, radiopharmaceuticals, stable medicinal products derived from human blood or human plasma, pre-mixes for the preparation of veterinary medicated feedingstuffs, and, where appropriate, vitamins, minerals, herbal remedies and homoeopathic medicinal products.

'GMP' is that part of quality assurance which ensures that products are consistently produced and controlled during manufacture to the quality standards appropriate to their intended use and as required by the marketing authorisation granted by the importing Party. For the purpose of this Sectoral Annex it includes the system whereby the manufacturer receives the specification of the product and/or process from the marketing authorisation holder or applicant and ensures that the medicinal product is made in compliance with this specification (equivalent to Qualified Person certification in the European Union).

2. With respect to medicinal products covered by the legislation of one Party ('regulating Party') but not the other, the manufacturing company may request the authority nominated by the relevant contact point of the regulating Party listed in point 12 of Section III, for the purpose of this Agreement, that an inspection be made by the locally competent inspection service. This provision will apply, inter alia, to the manufacture of active pharmaceutical ingredients and intermediate products and products intended for use in clinical trials, as well as jointly determined pre-marketing inspections. Operational arrangements are detailed under point 3(b) of Section III.

Certification of manufacturers

3. At the request of an exporter, importer or the competent authority of the other Party, the authorities responsible for granting manufacturing authorisations and for supervision of the manufacture of medicinal products will certify that the manufacturer:

— is appropriately authorised to manufacture the relevant medicinal product or to carry out the relevant specified manufacturing operation;

— is regularly inspected by the authorities, and

— complies with the national GMP requirements recognised as equivalent by the two Parties, referred to in Section I. Where different GMP requirements are used as a reference (in line with the provisions in point 3(b) of Section III), this is to be mentioned in the certificate.

The certificates will also identify the site(s) of manufacture (and contract testing laboratories, if any). The format of the certificate will be decided by the Joint Sectoral Group.

Certificates will be issued expeditiously, and the time taken should not exceed 30 calendar days. In exceptional cases, such as when a new inspection has to be carried out, this period may be extended to 60 calendar days.

Batch certification

4. Each batch exported will be accompanied by a batch certificate prepared by the manufacturer (self-certification) after a full qualitative analysis, a quantitative analysis of all the active constituents and all the other tests or checks necessary to ensure the quality of the product in accordance with the requirements of the marketing authorisation. This certificate will attest that the batch meets its specifications and will be kept by the importer of the batch. It will be made available upon request of the competent authority.

When issuing a certificate, the manufacturer will take account of the provisions of the current WHO certification scheme on the quality of pharmaceutical products moving in international commerce. The certificate will detail the agreed specifications of the product, the reference of the analytical methods and the analytical results. It will contain a statement that the batch processing and packaging records were reviewed and found to be in conformity with GMP. The batch certificate will be signed by the person responsible for releasing the batch for sale or supply, i.e. in the European Union the 'qualified person' as referred to in relevant European Union legislation. In New Zealand, the responsible person is named on the licence to manufacture issued under the relevant New Zealand legislation.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

Subject to Section III, general GMP inspections will be carried out against the GMP requirements of the exporting Party. The applicable legislative, regulatory and administrative provisions related to this Sectoral Annex are set out in the Table.

However, the reference quality requirements of products to be exported, including their manufacturing method and product specifications, will be those of the relevant product marketing authorisation granted by the importing Party.

Applicable legislative, regulatory and administrative provisions for the European Union	Applicable legislative, regulatory and administrative provisions for New Zealand
— Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products, as amended	— Medicines Act, 1981 — Medicines Regulations, 1984
— Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended	— New Zealand Code of Good Manufacturing Practice for Manufacture and Distribution of Therapeutic Goods, Parts 1, 2, 4 and 5
— Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, as amended	— Agricultural Compounds and Veterinary Medicines Act, 1997 — Agricultural Compounds and Veterinary Medicines Regulations, 2001
— Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use, as amended	— Agricultural Compounds and Veterinary Medicines (ACVM) Standard for Good Manufacturing Practice — Agricultural Compounds and Veterinary Medicines (ACVM) Guideline for Good Manufacturing Practice
— Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, as amended	— and any legislation adopted on the basis of, or that amends, the above legislation
— Guide to Good Distribution Practice (94/C 63/03)	
— Volume 4 — Guidelines for good manufacturing practices for medicinal products for human and veterinary use	

SECTION II

OFFICIAL INSPECTION SERVICES

The lists of official inspection services related to this Sectoral Annex have been jointly determined by the Parties and will be maintained by them. If a Party requests from the other Party a copy of its latest lists of official inspection services, the requested Party will provide the requesting Party with a copy of those lists within 30 calendar days of the date of receipt of the request.

SECTION III

OPERATIONAL PROVISIONS

1. **Transmission of inspection reports**

Upon reasoned request, the relevant inspection services will forward a copy of the last inspection report of the manufacturing or control site, in the case where analytical operations are contracted out. The request may concern a 'full inspection report' or a 'detailed report' (see point (2). Each Party will deal with these inspection reports with the degree of confidentiality requested by the Party of origin.

If the manufacturing operations of the medicinal product in question have not been inspected recently, i.e. when the last inspection dates back to more than two years or a particular need to inspect has been identified, a specific and detailed inspection may be requested. Parties will ensure that inspection reports are forwarded in no more than 30 calendar days, this period being extended to 60 calendar days should a new inspection be carried out.

2. **Inspection reports**

A 'full inspection report' comprises a Site Master File (compiled by the manufacturer or by the inspectorate) and a narrative report by the inspectorate. A 'detailed report' responds to specific queries about a firm by the other Party.

3. **Reference GMP**

(a) Manufacturers will be inspected against the applicable GMP of the exporting Party (see Section I).

(b) With respect to medicinal products covered by the pharmaceutical legislation of the importing Party but not the exporting one, the locally competent inspection service willing to carry out an inspection of the relevant manufacturing operations will inspect against its own GMP or, in the absence of specific GMP requirements, against the applicable GMP of the importing Party. This will also be the case when the locally applicable GMP are not considered equivalent, in terms of quality assurance of the finished product, to the GMP of the importing Party.

Equivalence of GMP requirements for specific products or classes of products (e.g. investigational medicinal products, starting materials) will be determined according to a procedure established by the Joint Sectoral Group.

4. **Nature of inspections**

(a) Inspections will routinely assess the compliance of the manufacturer with GMP. These are called general GMP inspections (also regular, periodic, or routine inspections).

(b) 'Product- or process-oriented' inspections (which may be 'pre-marketing' inspections as relevant) focus on the manufacture of one or one series of product(s) or process(es) and include an assessment of the validation of and compliance with specific process or control aspects as described in the marketing authorisation. Where necessary, relevant product information (the quality dossier of an application/authorisation dossier) will be provided in confidence to the inspectorate.

5. **Inspection/establishment fees**

The regime of inspection/establishment fees is determined by the manufacturer's location. Inspection/establishment fees will not be charged to manufacturers located on the territory of the other Party for products covered by this Sectoral Annex.

6. **Safeguard clause for inspections**

Each Party reserves the right to conduct its own inspection for reasons identified to the other Party. Such inspections are to be notified in advance to the other Party, which has the option of joining the inspection. Recourse to this safeguard clause should be an exception. Should such an inspection take place, inspection costs may be recovered.

7. **Exchange of information between authorities and approximation of quality requirements**

In accordance with the general provisions of this Agreement, the Parties will exchange any relevant information necessary for the ongoing mutual recognition of inspections. For the purposes of demonstration of capability in cases of significant changes to regulatory systems in either of the Parties, additional specific information may be requested by either Party in relation to an official inspection service. Such specific requests may cover information on training, inspection procedures, general information and document exchange, and transparency of agency audits of official inspection services relevant to the operation of this Sectoral Annex. Such requests should be made through and managed by the Joint Sectoral Group as part of an ongoing maintenance programme.

In addition, the relevant authorities in New Zealand and in the European Union will keep each other informed of any new technical guidance or changes to inspection procedures. Each Party will consult the other before their adoption.

8. **Official batch release**

The official batch release procedure is an additional verification of safety and efficacy of immunological medicinal products (vaccines) and blood derivatives, carried out by the competent authorities before the distribution of each batch of product. This Agreement does not encompass this mutual recognition of official batch releases. However, when an official batch release procedure applies, the manufacturer will provide, at the request of the importing Party, the official batch release certificate if the batch in question has been tested by the control authorities of the exporting Party.

For the European Union, the official batch release procedure for medicinal products for human use is published by the European Directorate for the Quality of Medicines & HealthCare. For New Zealand, the official batch release procedure is specified in document 'WHO Technical Report Series, No 822, 1992'.

9. **Inspectors' training**

In accordance with the general provisions of this Agreement, training sessions for inspectors, organised by the authorities, will be accessible to inspectors of the other Party. The Parties will keep each other informed of these sessions.

10. **Joint inspections**

In accordance with the general provisions of this Agreement, and by mutual arrangement between the Parties, joint inspections may be authorised. These inspections are intended to develop common understanding and interpretation of practice and requirements. The setting up of these inspections and their form will be established through procedures approved by the Joint Sectoral Group.

11. **Alert system**

Contact points will be designated by the Parties to permit competent authorities and manufacturers to inform the authorities of the other Party with the appropriate speed in case of quality defects, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure will be jointly established.

The Parties will ensure that any suspension or withdrawal (total or partial) of a manufacturing authorisation, based on non-compliance with GMP and which could affect the protection of public health, is communicated to the other Party with the appropriate degree of urgency.

12. **Contact points**

For the purpose of this Sectoral Annex, the contact points for any technical question, such as exchange of inspection reports, inspector training sessions, technical requirements, will be:

FOR NEW ZEALAND:

For medicinal products for human use:

Group Manager
Medicines and Medical Devices Safety Authority (Medsafe)
PO Box 5013
Wellington
New Zealand
Tel. 64-4-819 6874
Fax 64-4-819 6806

For medicinal products for use in animals:

Director, Approvals and ACVM Standards
Ministry of Agriculture and Forestry
(MAF) PO Box 2526
Wellington 6140
New Zealand
Tel. 64-4-894 2541
Fax 64-4-894 2501

FOR THE EUROPEAN UNION: The Director of the European Medicines Agency
7 Westferry Circus
Canary Wharf
London E14 4HB
United Kingdom
Tel. 44-171-418 8400
Fax 44-171-418 8416

13. **Joint Sectoral Group**

A Joint Sectoral Group made up of representatives of the Parties will be established under this Sectoral Annex. It will be responsible for the effective functioning of this Sectoral Annex. It will report to the Joint Committee as the Joint Committee will determine.

The Joint Sectoral Group will determine its own rules of procedure. It will take its decisions and adopt its recommendations by consensus. It may decide to delegate its tasks to subgroups.

14. **Divergence of views**

Both Parties will use their best endeavours to resolve any divergence of views concerning, inter alia, compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Joint Sectoral Group.

SECTION IV

CHANGES TO THE LIST OF OFFICIAL INSPECTION SERVICES

The Parties recognise the need for this Sectoral Annex to accommodate change, particularly with regard to the entry of new official inspection services or changes in the nature or role of established competent authorities. Where significant changes have occurred with regard to official inspection services, the Joint Sectoral Group will consider what, if any, additional information is required to verify programmes and establish or maintain mutual recognition of inspections, in accordance with point 7 of Section III.'.

11. The Sectoral Annex on medical devices is replaced by the following:

'SECTORAL ANNEX ON MEDICAL DEVICES TO THE EUROPEAN COMMUNITY — NEW ZEALAND AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT

SCOPE AND COVERAGE

The provisions of this Sectoral Annex will apply to the following products:

Products for export to the European Union	Products for export to New Zealand
(1) All medical devices: (a) manufactured in New Zealand; and (b) subject to third party conformity assessment procedures, both product and quality systems-related; and (c) provided for in Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended; and	(1) All medical devices: (a) manufactured in the European Union; and (b) subject to third party conformity assessment procedures, both product and quality systems-related, or subject to other requirements under the legislation listed in Section I, as amended.

Products for export to the European Union	Products for export to New Zealand
(d) provided for in Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended.	
(2) For the purposes of paragraph 1:	(2) For the purposes of paragraph 1:
(a) medical devices provided for in the Appendix are excluded; and	(a) medical devices provided for in the Appendix are excluded; and
(b) unless otherwise provided for or by mutual arrangement by the Parties, 'manufacture' of a medical device does not include:	(b) unless otherwise provided for or by mutual arrangement by the Parties, 'manufacture' of a medical device does not include:
(i) restoration or renovation processes such as repairing, re-conditioning, overhauling or refurbishing; or	(i) restoration or renovation processes such as repairing, re-conditioning, overhauling or refurbishing; or
(ii) operations such as pressing, labelling, ticketing, packaging and preparation for sale, conducted alone or in combination with each other; or	(ii) operations such as pressing, labelling, ticketing, packaging and preparation for sale, conducted alone or in combination with each other; or
(iii) quality control inspections alone; or	(iii) quality control inspections alone; or
(iv) sterilisation alone.	(iv) sterilisation alone.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Union with which New Zealand-designated conformity assessment bodies will assess compliance	The legislative, regulatory and administrative requirements of New Zealand with which European Union-designated conformity assessment bodies will assess compliance
— Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices, as amended	— Radiocommunications Act 1989 and Regulations made pursuant to that Act
— Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended	— Electricity Act 1992 and Regulations made pursuant to that Act
— and any European Union legislation adopted on the basis of these Directives	— Medicines Act 1981
	— Medicines Regulations 1984
	— Medicines (Database of Medical Devices) Regulations 2003
	— and any legislation adopted on the basis of, or that amends, the above legislation

SECTION II

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING CONFORMITY ASSESSMENT BODIES UNDER THIS SECTORAL ANNEX

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
— Ministry of Health	— *Belgium* Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
	Agence Fédérale des Médicaments et des Produits de Santé – Federaal Agentschap voor Geneesmiddelen en Gezondheidsproducten
	— *Bulgaria*
	Държавна агенция за метрологичен и технически надзор
	— *Czech Republic*
	Úřad pro technickou normalizaci, metrologii a státní zkušebnictví
	— *Denmark*
	Indenrigs- og Sundhedsministeriet
	Lægemiddelstyrelsen
	— *Germany*
	ZLG — Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten, Bonn
	ZLS — Zentralstelle der Länder für Sicherheitstechnik, München
	— *Estonia*
	Majandus- ja Kommunikatsiooniministeerium
	— *Ireland*
	Department of Health
	Irish Medicines Board
	— *Greece*
	Υπουργείο Υγείας και Κοινωνικής Αλληλεγγύης
	Εθνικός Οργανισμός Φαρμάκων
	— *Spain*
	Ministerio de Sanidad, Política Social e Igualdad
	Agencia Española de Medicamentos y Productos Sanitarios
	— *France*
	Ministère de la Santé
	Agence Française de Sécurité Sanitaire des produits de Santé
	Agence Nationale du Médicament Vétérinaire
	— *Italy*
	Ministero della Salute – Dipartimento dell' Innovazione – Direzione Generale Farmaci e Dispositivi Medici
	— *Cyprus*
	The Drugs Council, Pharmaceutical Services (Ministry of Health)
	Veterinary Services (Ministry of Agriculture)

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
	— *Latvia* Zāļu valsts aģentūra Veselības ministrija — *Lithuania* Lietuvos Respublikos sveikatos apsaugos ministerija — *Luxembourg* Ministère de la Santé Division de la Pharmacie et des Médicaments — *Hungary* Országos Gyógyszerészeti Intézet — *Malta* Direttorat tal-Affarijiet Regolatorji, Awtorità Maltija dwar l-i*Standards* — *Netherlands* Ministerie van Volksgezondheid, Welzijn en Sport Inspectie voor de Gezondheidszorg — *Austria* Bundesministerium für Gesundheit Bundesamt für Sicherheit im Gesundheitswesen — *Poland* Ministerstwo Zdrowia Urząd Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych — *Portugal* INFARMED:I.P. (Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.) — *Romania* Ministerul Sănătății – Departament Dispozitive Medicale — *Slovenia* Ministrstvo za zdravje Javna agencija Republike Slovenije za zdravila in medicinske pripomočke — *Slovakia* Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky — *Finland* Sosiaali- ja terveysministeriö Sosiaali- ja terveysalan lupa- ja valvontavirasto (Valvira)

For the conformity assessment bodies designated by New Zealand	For the conformity assessment bodies designated by the European Union
	— *Sweden* Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — *United Kingdom* Medicines and Healthcare products Regulatory Agency

SECTION III

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by New Zealand in designating conformity assessment bodies to assess products against the European Union's requirements	The procedures to be followed by the European Union in designating conformity assessment bodies to assess products against New Zealand's requirements
Conformity assessment bodies to be designated for the purposes of this Sectoral Annex will meet the requirements of the Directives listed in Section I, taking into account Annex II to Decision No 768/2008/EC of the European Parliament and of the Council of 9 July 2008 on a common framework for the marketing of products, as amended, and be designated on the basis of the procedures defined in the Annex to this Agreement. This may be demonstrated through: (a) Product certification bodies operating according to the requirements of EN 45011 or ISO Guides 28 and 40, and either: — accredited by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ), or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to this Agreement. (b) Quality System certification bodies operating according to the requirements of EN 45012 or ISO Guide 62, and either: — accredited by JAS-ANZ, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to this Agreement. (c) Inspection bodies operating according to the requirements of ISO/IEC 17020, and either: — accredited by the Testing Laboratory Registration Council of New Zealand or any other body established by law in New Zealand which replaces it and which has the same functions, or — able to demonstrate competence by other means in accordance with Sections A and B of the Annex to this Agreement. Pursuant to point 5.2 of Section IV, designation for high-risk devices listed in point 5.1 of that Section will occur on the basis of a confidence-building programme.	1. The procedures for designating conformity assessment bodies will be consistent with the principles and procedures set out in the Annex to this Agreement. 2. The following procedures are deemed to be consistent with those set out in the Annex to this Agreement: (a) Certification bodies: — accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement (MLA) for certification of products, — members of the Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE) CB Scheme, — accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement, or — able to demonstrate competence by other means in accordance with Section A and B of the Annex to this Agreement. (b) Testing laboratories: — accredited by accreditation bodies which are signatories to the EA MLA for calibration and testing laboratories, — recognised within the IECEE CB Scheme, or — able to demonstrate competence by other means in accordance with Section A and B of the Annex to this Agreement. Pursuant to point 5.2 of Section IV, designation for high-risk devices listed in point 5.1 of that Section will occur on the basis of a confidence-building programme.

SECTION IV

ADDITIONAL PROVISIONS

1. **New legislation**

The Parties note New Zealand's intention to introduce new legislation concerning medical devices, and jointly decide that the provisions of this Sectoral Annex will apply to this legislation upon its entry into force in New Zealand.

The Parties jointly declare their intention to extend the scope of this Sectoral Annex to in vitro diagnostic devices as soon as New Zealand's new legislation concerning medical devices is in place.

2. **Exchange of information**

The Parties will inform each other of incidents in the context of the medical device vigilance procedure, or with regard to matters concerning product safety. The Parties will also inform each other of:

— certificates withdrawn, suspended, restricted or revoked, and

— any legislation or amendment to existing legislation adopted on the basis of the legal texts listed in Section I.

The contact points through which the information can be passed are:

New Zealand:	The Manager Medicines and Medical Devices Safety Authority (Medsafe) PO Box 5013 Wellington New Zealand Tel. 64-4-819 6874 Fax 64-4-819 6806 and Group Manager Energy Safety and Radio Spectrum Management Ministry of Economic Development (MED) P.O. Box 1473 Wellington New Zealand Tel. 64-4-472-0030 Fax 64-4-471-0500
European Union	European Commission Directorate-General for Health and Consumers Rue de la Loi/Wetstraat 200 B-1049 Brussels Tel. 32-2-299 11 11

The Parties may exchange information on the consequences of the establishment of the European Database on Medical Devices (Eudamed).

In addition, the Medicines and Medical Devices Safety Authority will advise of any certificates issued.

3. **Subcontracting**

Where required by New Zealand legislative, regulatory and administrative provisions, European Union conformity assessment bodies subcontracting all or part of the testing will subcontract only to testing laboratories accredited in accordance with point 2 of Section III.

4. **Recording of approvals granted**

In addition to the requirements imposed by the Annex to this Agreement on the designation of a conformity assessment body, the relevant European Union designating authority will provide to New Zealand, in respect of each designated conformity assessment body, details of the method that such conformity assessment body intends to adopt to record the fact that an approval required by the Secretary under the Electricity Act 1992 (and Regulations made pursuant to that Act) for fittings or appliances to be sold or offered for sale in New Zealand has been granted.

5. **Confidence-building with respect to high-risk devices**

5.1. A confidence-building process for the purpose of strengthening confidence in the designating systems of each of the Parties will apply for the following medical devices:

— active implantable devices as defined in the legislation referred to in Section I;

— devices that are classified as class III devices under the legislation referred to in Section I;

— medical devices that are implantable intra-ocular lenses;

— medical devices that are intra-ocular visco elastic fluids, and

— medical devices that are a barrier indicated for contraception or prevention of the sexual transmission of disease.

5.2. The Parties will establish a detailed programme to this effect involving the Medicines and Medical Devices Safety Authority and the European Union's competent authorities.

5.3. The confidence-building period will be reviewed after two years commencing from the date this Sectoral Annex, as amended, becomes effective.

5.4. Additional specific requirements for regulatory progress:

5.4.1. In pursuance of Articles 2, 7(1), 8(1) and 9(1) of this Agreement, either Party may request additional specific requirements in relation to the conformity assessment bodies for the purposes of demonstration of experience in the evolving regulatory systems.

5.4.2. These specific requirements may include training, observed conformity assessment body audits, visits and information and document exchange, including audit reports.

5.4.3. These requirements may likewise be applicable in relation to the designation of a conformity assessment body in accordance with this Agreement.

6. **Joint Sectoral Group**

A Joint Sectoral Group made up of representatives of the Parties will be established under this Sectoral Annex. It will be responsible for the effective functioning of this Sectoral Annex. It will report to the Joint Committee as the latter will determine.

The Joint Sectoral Group will determine its own rules of procedure. It will take its decisions and adopt its recommendations by consensus. It may decide to delegate its tasks to subgroups.

7. **Divergence of views**

Both Parties will use their best endeavours to resolve any divergence of views concerning, inter alia, compliance of manufacturers and conclusions of conformity assessment reports. Unresolved divergences of view will be referred to the Joint Sectoral Group.

Appendix

The provisions of this Sectoral Annex will not apply to the following devices:

— medical devices that contain or are manufactured using cells, tissues or tissue derivatives of animal origin that have been rendered non-viable, where the safety with regard to viruses or other transferable agents requires validated methods for elimination or viral inactivation in the course of the manufacturing process;

— medical devices that contain tissues, cells or substances of microbial, bacterial or recombinant origin and are intended for use in or on the human body;

— medical devices incorporating tissues or tissue derivatives of human origin;

— medical devices incorporating stable derivatives of human blood or human plasma that are liable to act on the human body in a way that is ancillary to the device;

— medical devices that incorporate, or intend to incorporate, as an integral part, a substance that, if used separately, might be considered to be a medicine that is intended to act on a patient in a way that is ancillary to the device, and

— medical devices that are intended by the manufacturer specifically to be used for chemical disinfection of another medical device, except for sterilisers using dry heat, moist heat or ethylene oxide.

Both Parties may decide by common arrangement to extend the application of this Sectoral Annex to the aforementioned medical devices.'.

Article 2

Entry into force

This Agreement shall enter into force on the first day of the second month following the date on which the Parties have exchanged diplomatic notes confirming the completion of their respective procedures for entry into force of this Agreement

Done at Brussels, in duplicate, on 23 February 2012 in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish languages, each text being equally authentic.

За Европейския съюз
Por la Unión Europea
Za Evropskou unii
For Den Europæiske Union
Für die Europäische Union
Euroopa Liidu nimel
Για την Ευρωπαϊκή Ένωση
For the European Union
Pour l'Union européenne
Per l'Unione europea
Eiropas Savienības vārdā –
Europos Sąjungos vardu
Az Európai Unió részéről
Għall-Unjoni Ewropea
Voor de Europese Unie
W imieniu Unii Europejskiej
Pela União Europeia
Pentru Uniunea Europeană
Za Európsku úniu
Za Evropsko unijo
Euroopan unionin puolesta
För Europeiska unionen

За Нова Зеландия
Por Nueva Zelanda
Za Nový Zéland
For New Zealand
Für Neuseeland
Uus-Meremaa nimel
Για τη Νέα Ζηλανδία
For New Zealand
Pour la Nouvelle-Zélande
Per la Nuova Zelanda
Jaunzēlandes vārdā –
Naujosios Zelandijos vardu
Uj-Zéland részéről
Għal New Zealand
Voor Nieuw-Zeeland
W imieniu Nowej Zelandii
Pela Nova Zelândia
Pentru Noua Zeelandă
Za Nový Zéland
Za Novo Zelandijo
Unden-Seelannin puolesta
För Nya Zeeland