EUROPEAN COMMISSION

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2010/0146 (NLE)

Proposal for a

COUNCIL DECISION

on the conclusion of the Agreement between the European Union and Australia amending the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia

EXPLANATORY MEMORANDUM

I. THE AMENDMENT

1. Background

The Agreement between the European Community and Australia ('the Parties') on mutual recognition in relation to conformity assessment, certificates and markings[1] (hereinafter 'the Agreement on Mutual Recognition') entered into force on 1 January 1999[2]. With a view to further improving and simplifying the functioning of the Agreement on Mutual Recognition, the Parties have decided to amend some of its provisions.

On the basis of the negotiating directives included in the specific decision of the Council of 21 September 1992 authorising the Commission to negotiate agreements between the European Economic Community and certain third countries on mutual recognition relating to conformity assessment, as amended by the specific decisions adopted by the Council on 26 May 1997 and 8 July 2002, the Commission has negotiated and initialled an Amendment to the Agreement on Mutual Recognition (hereinafter 'the Amendment').

The text of the Amendment is attached to this proposal. The Commission proposes that the Council authorise the signature of the Amendment on behalf of the Union.

The Agreement between the European Community and New Zealand on mutual recognition in relation to conformity assessment[3] is in effect identical to the Agreement on Mutual Recognition with Australia. A parallel Agreement amending the Agreement with New Zealand will be proposed.

2. Assessment of the Amendment

The amendments are intended to allow greater flexibility in the structure of Sectoral Annexes to the Agreement on Mutual Recognition, to remove unnecessary restrictions on trade between the Parties, to reduce the administrative burden related to management of the Agreement and to facilitate and clarify the operation of the Agreement.

In addition, the Sectoral Annexes on medicinal products GMP inspection and batch certification and on medical devices have been superseded by changes in technical and administrative practice and by changes in the organisations listed therein, and the opportunity has been taken to revise them.

There are no financial implications to this proposal. The Amendment will be published in the Official Journal of the European Union.

A detailed assessment of the Amendment follows.

1. In order to remove unnecessary restrictions on trade, the restriction in Article 4 of the application of the Agreement to industrial products that originate in the Parties according to non-preferential rules of origin will be deleted. As amended, the

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1 OJ L 229, 17.8.1998, p. 3.
2 OJ L 5, 9.1.1999, p. 74.
3 Ibid., p. 62.

Agreement on Mutual Recognition will apply to all products covered by it, irrespective of their origin.

2. The references to the Chair of the Joint Committee will be deleted from Articles 8 and 12, in order to reflect the fact that the Joint Committee is co-chaired by the Parties.

3. In order to simplify operation of the Agreement on Mutual Recognition, a simpler procedure for the recognition, withdrawal of recognition and suspension of conformity assessment bodies will be set up in Article 12. As a result, a decision by a designating authority to designate or withdraw designation of a conformity assessment body will no longer need to be given effect by an amendment to a Sectoral Annex; the need for the Joint Committee to take action will be limited to cases that have been contested by the other Party under Article 8.

4. In order to make timely adaptations to the Sectoral Annexes to take account of technical progress and other factors such as enlargement of the European Union, Article 12 will also be amended in order to explicitly empower the Joint Committee to amend the Sectoral Annexes in areas other than to give effect to the decision by a designating authority to designate or withdraw designation of a particular conformity assessment body, and also to adopt new Sectoral Annexes.

5. Article 3 will be amended in order to reflect the changes to Article 12 and to allow greater flexibility in the structure of Sectoral Annexes to the Agreement on Mutual Recognition.

6. The wording of Articles 6, 7, 8, 9 and 15, and of paragraphs 9 and 10 of the Annex, have been changed in order to reflect the amendments to Article 12.

7. The Sectoral Annex on medicinal products GMP inspection and batch certification has been revised to take account of developments in technical and administrative practice, changes introduced by the Amendment to the main body of the Agreement on Mutual Recognition, updates in the organisations listed, and changes to the Parties' legislation affecting this sector. The principle of operation of this Sectoral Annex remains unchanged.

8. The Sectoral Annex on medical devices has been revised to take account of developments in technical and administrative practice, changes introduced by the Amendment to the main body of the Agreement on Mutual Recognition, updates in the organisations listed, and changes to the Parties' legislation affecting this sector. The principle of operation of this Sectoral Annex remains unchanged.

3. Relations with EFTA/EEA Member Countries

In accordance with the information and consultation procedures set out in the Agreement on the European Economic Area and Protocol 12 to that Agreement, the Commission has informed EFTA/EEA Member Countries of progress in the negotiations and the final result.

II. THE PROPOSAL FOR A COUNCIL DECISION

The Agreement between the European Union and Australia amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and Australia was signed by the Commission on [ ].

The Commission therefore proposes that the Council, with the consent of the Parliament, adopts the attached Decision on the conclusion of the amendment to the Agreement.

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Proposal for a

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on the conclusion of an Agreement between the European Community and Australia amending the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(4), first subparagraph, in conjunction with Article 218(6)(a)thereof,

Having regard to the proposal from the Commission,

Having regard to the consent of the European Parliament[4],

Whereas:

(1) The Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia[5] (hereinafter 'the Agreement on Mutual Recognition') entered into force on 1 January 1999[6].

(2) In accordance with Council Decision 2010/XXX of [...][7], the Agreement between the European Union and Australia amending the Agreement on mutual recognition in relation to conformity assessment between the European Community and Australia (hereinafter referred to as 'the Agreement') was signed by the Commission on [ ], subject to its conclusion at a later date.

(3) The Agreement should be concluded,

HAS ADOPTED THIS DECISION:

Article 1

The Agreement between the European Union and Australia amending the Agreement on mutual recognition in relation to conformity assessment, certificates and markings between the European Community and Australia (hereinafter referred to as 'the Agreement') is hereby concluded.

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4 OJ C […], […], p. […].
5 OJ L 229, 17.8.1998, p. 3.
6 OJ L 5, 9.1.1999, p. 74.
7 OJ L […], […], p. […].

The text of the Agreement to be concluded is attached to this Decision.

Article 2

The President of the Council shall designate the person empowered to proceed, on behalf of the European Union, to transmitting the diplomatic note provided for in Article 14 of the Agreement on Mutual Recognition, in order to express the consent of the European Union to be bound by the Agreement.

Article 3

This Decision shall enter into force on the day of its adoption. It shall be published in the Official Journal of the European Union.

The date of entry into force of the Agreement shall be published in the Official Journal of the European Union.

Done at Brussels, […]

For the Council
The President
[…]

ANNEX I

AGREEMENT

amending the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between the European Community and Australia

THE EUROPEAN UNION AND AUSTRALIA, hereinafter referred to as 'the Parties',

HAVING concluded an Agreement on mutual recognition in relation to conformity assessment, certificates and markings signed in Canberra on 24 June 1998 (hereinafter referred to as 'the Agreement');

NOTING the need to simplify the operation of the Agreement;

NOTING the need to clarify the status of the Sectoral Annexes of the Agreement;

WHEREAS Article 3 of the Agreement sets out the form of the Sectoral Annexes in detail;

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

WHEREAS Article 12 of the Agreement 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 refer to the Chair of the Joint Committee;

WHEREAS Article 12 of the Agreement 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 should be amended, both to reflect the changes proposed to Article 12 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, 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 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;

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

CONSIDERING that in order to make timely adaptations to the Sectoral Annexes in order 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 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;

RECOGNISING that the Parties may need to undertake certain domestic procedures before amendments to Sectoral Annexes or the adoption of new Sectoral Annexes take effect;

CONSIDERING that in order to simplify the operation of the Agreement, the need for the Joint Committee to take action 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;

CONSIDERING that in order to simplify the operation of the Agreement, a simpler procedure for the recognition, withdrawal of recognition, and suspension of Conformity Assessment Bodies should be set up in Article 12, and the position regarding conformity assessment carried out by bodies afterwards suspended or withdrawn should be clarified,

HAVE AGREED TO AMEND THE AGREEMENT AS FOLLOWS:

Article 1

Amendments to the Agreement

The Agreement is 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

The provisions of this Agreement shall apply to conformity assessment of products specified in the statement of scope and coverage in each Sectoral Annex.'

3. Article 6(1) is replaced by the following:

'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 of and withdraw the designation of such bodies.'

4. Article 6(2) is replaced by the following:

'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.'

5. Article 6(3) is deleted.

6. 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.'

7. Article 8(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 the Joint Committee'.

8. Article 8(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 competence or compliance was challenged until either agreement has been 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 competence and compliance of the Conformity Assessment Body.'

9. 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 Organisation 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 in Article 9(3), notify the other Party of the new provisions at least 60 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 to eliminate an immediate risk posed by a product covered by a Sectoral Annex, it shall notify the other Party of the measures and the reasons for the imposition of the measures immediately, or as otherwise specified in a Sectoral Annex.'

10. Article 12(3) is replaced by the following:

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

11. Article 12(4) is replaced by the following:

'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;

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

12. Article 12(5) is replaced by the following:

'5. Any amendments to 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 for both Parties on the date on which the Joint Committee has received notification from each Party confirming

completion of their respective procedures for the amendments or new Sectoral Annex to take effect, unless otherwise mutually determined in writing by the Parties.'

13. Article 12(6) is replaced by the following:

'6. The following procedure shall apply in relation to the designation of a Conformity Assessment Body:

(a) a Party wishing to designate any Conformity Assessment Body shall forward its proposal to the other Party in writing, to that effect, adding supporting documentation as defined by the Joint Committee to the request;

(b) in the event that the other Party consents or upon the expiry of 60 days without an objection having been lodged in accordance with the procedures of 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 a 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 Conformity Assessment Body shall be valid from the date on which the Conformity Assessment Body becomes a designated Conformity Assessment Body in accordance with this Agreement;

(e) either Party may suspend, remove suspension 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 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.'

14. Article 12(7) is replaced by the following:

'7. In the event that the designation of a Conformity Assessment Body is suspended or withdrawn, conformity assessment carried out by that Conformity Assessment 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.'

15. After Article 12(8), the following is inserted into the Agreement as Article 12(9):

'9. The Joint Committee shall maintain current Sectoral Annexes and provide these to Parties upon amendments taking effect.'

16. Article 15(1) is replaced by the following:

'1. The Annex to this Agreement forms an integral part thereof. The Sectoral Annexes form the administrative arrangements for the implementation of this Agreement and do not have treaty status.'

17. Article 15(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. Any additional Sectoral Annexes will come into effect in accordance with Article 12(5).'

18. Article 15(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 and come into effect in accordance with Article 12(5).'

19. Paragraph 9 of the Annex 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 Conformity Assessment Bodies to be designated, suspended or withdrawn. Designation, suspension or withdrawal of designation of Conformity Assessment Bodies shall take place in accordance with the provisions of this Agreement and the rules of procedure of the Joint Committee.'

20. Paragraph 10 of the Annex 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 email 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.'

21. The Sectoral Annex on medicinal products GMP inspections and batch certification is deleted and replaced by the following text:

'SECTORAL ANNEX ON MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

SCOPE AND COVERAGE

1. The Parties mutually establish that the provisions of this Sectoral Annex will cover all medicinal products which are industrially manufactured in Australia and 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 Australia 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 homeopathic 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 Section III item 12], 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 mutually determined pre-marketing inspections. Operational arrangements are detailed under Section III, item 3 b.

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 may be used as a reference (in line with the provisions in Section III, item 3 b), 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 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 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 EU legislation. In Australia, the responsible persons are for manufacturing quality control as specified in the relevant Australian legislation.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

Subject to Section III "Operational provisions", 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 listed in the Appendix.

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.

SECTION II

OFFICIAL INSPECTION SERVICES

The lists of official inspection services related to this Sectoral Annex have been mutually established by the Parties and will be maintained by them. If a Party requests the other Party for a copy of its latest lists of official inspection services, the requested Party will provide the requesting Party a copy of those lists within 30 days of the date of receipt of that 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 case analytical operations are contracted out. The request may concern a "full inspection report" or a "detailed report" (see item 2 below). 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 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

The Parties mutually acknowledge that 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 the 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 Australia and in the EuropeanUnion 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 will 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 procedures for medicinal products for human use are published by the European Directorate for the Quality of Medicines & HealthCare. For Australia, 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 the Agreement, training sessions for inspectors, organised by the authorities, will be accessible to inspectors of the other Party. The Parties to the Agreement will keep each other informed of these sessions.

10. Joint inspections

In accordance with the general provisions of the 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 agreed between 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 mutually 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, are communicated to each other 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, inspectors training sessions, technical requirements, will be:

For Australia:
For medicinal products for human use:
The Head of Office
Therapeutic Goods Administration
Department of Health and Ageing
PO Box 100
Woden ACT 2606
Australia
Tel: 61-6-232-8622
Fax: 61-6-232-8426

For medicinal products for use in animals:
The Manager, GMP Section
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604
Australia
Tel: 61-6210-4803
Fax: 61-6210-4741

For the European Union:
The Director of the European Agency for the Evaluation of Medicinal Products
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 mutually 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 Section III, item 7.

In accordance with the provisions of the Agreement, the Australian veterinary medicinal product manufacturers will be inspected by the Therapeutic Goods Administration (TGA) on behalf of the Australian Pesticides and Veterinary Medicines Authority, according to the current Australian code of GMP and the EC GMP Guide for veterinary medicinal products. The European Union will recognise the conclusions of inspections carried out by the TGA and Australian manufacturers' certifications of batch conformity. Should the Australian Pesticides and Veterinary Medicines Authority (APVMA) begin to carry out inspections itself, inspection reports will also be routinely transmitted to the importing Party until there has been a satisfactory verification of the APVMA GMP inspection programme.

Appendix 1

LIST OF APPLICABLE LEGISLATIVE, REGULATORY AND ADMINISTRATIVE PROVISIONS

For the European Union:

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as extended, widened and amended

Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, as extended, widened and amended

Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products, as widened and amended

Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use

Commission Directive 91/412/EEC of 23 July 1991 laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products

Council Regulation No (EEC) 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use & Guide to Good Distribution Practice

Current version of the Guide to Good Manufacturing Practice, Rules Governing Medicinal Products in the European Community, Annex IV

For Australia:

For products for human use:

Therapeutic Goods Act 1989, and Regulations, Orders and Determinations thereunder, including Orders setting standards such as labelling, the Determination establishing Manufacturing Principles and Australian Codes of Good Manufacturing Practice

For products for veterinary use:

Legislation — Commonwealth:

- Agricultural and Veterinary Chemicals (Administration) Act 1992
- Agricultural and Veterinary Chemicals Act 1994
- Agricultural and Veterinary Chemicals Code Act 1994
- Agricultural and Veterinary Chemicals (Administration) Regulations 1995
- Agricultural and Veterinary Chemicals Instrument No 1 (Manufacturing Principles) 2007
- Agricultural and Veterinary Chemicals Code Regulations 1995

Legislation — New South Wales:

- Stock Foods Act 1940
- Stock Medicines Act 1989
- Public Health Act 1991
- Poisons and Therapeutic Goods Act 1966
- Pesticides Act 1979
- Agricultural and Veterinary Chemicals (NSW) Act 1994

and including any regulations, orders or instruments made under this legislation

Legislation — Victoria:

- Animal Preparations Act, 1987
- Health Act, 1958
- Drugs, Poisons and Controlled Substances Act, 1981
- Agricultural and Veterinary Chemicals (Victoria) Act 1994

and including any regulations, orders or instruments made under this legislation

Legislation — Queensland:

- Agricultural Standards Act 1994
- Stock Act 1915
- Health Act 1937
- Agricultural and Veterinary Chemicals (Queensland) Act 1994

and including any regulations, orders or instruments made under this legislation

Legislation — South Australia:

- Stock Medicines Act 1939-1978
- Stock Foods Act 1941
- Dangerous Substances Act 1986
- Controlled Substances Act 1984
- Stock Diseases Act 1934
- Agricultural and Veterinary Chemicals (SA) Act 1994

and including any regulations, orders or instruments made under this legislation

Legislation — Western Australia:

- Veterinary Preparations and Animal Feeding Stuffs Act 1976–1982
- Poisons Act 1964-1981
- Health Act 1911
- Agricultural and Veterinary Chemicals (WA) Act 1995
- Health (Pesticides) Regulations 1956

and including any regulations, orders or instruments made under this legislation

Legislation — Tasmania:

- Veterinary Medicines Act 1987
- Poisons Act 1971
- Public Health Act 1997
- Agricultural and Veterinary Chemicals (Tasmania) Act 1994
- Pesticides Act 1968

and including any regulations, orders or instruments made under this legislation

Legislation — Northern Territory:

- Poisons and Dangerous Drugs Act 1983
- Therapeutic Goods and Cosmetics Act 1986
- Stock Diseases Act 1954
- Agricultural and Veterinary Chemicals (NT) Act 1994

and including any regulations, orders or instruments made under this legislation

Legislation — Australian Capital Territory

- Environment Protection Act, 1997

and including any regulations, orders or instruments made under this legislation.’

22. The Sectoral Annex on medical devices is deleted and replaced by the following text:

'SECTORAL ANNEX ON
MEDICAL DEVICES
TO THE EUROPEAN COMMUNITY-AUSTRALIA AGREEMENT
ON MUTUAL RECOGNITION IN RELATION TO
CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

The Parties mutually establish that the provisions of this Sectoral Annex will apply to the following products:

Products for export to the European Union

(1) All medical devices:

(a) manufactured in Australia; 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, as last amended, on the approximation of the laws of the Member States relating to active implantable medical devices; and

(d) provided for in Council Directive 93/42/EEC of 14 June 1993, as last amended, concerning medical devices.

(2) For the purposes of paragraph (1):

(a) medical devices provided for in Appendix 1 are excluded; and

(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

(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

(iv) sterilisation alone.

Products for export to Australia

(1) All medical devices:

(a) manufactured in the European Union; and

(b) subject to conformity assessment procedures, both product- and quality systems-related, under the Australian Therapeutic Goods Act 1989 and Therapeutic Goods Regulations, as last amended.

(2) For the purposes of paragraph (1):

(a) medical devices provided for in Appendix 1 are excluded; and

(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

(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

(iv) sterilisation alone.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

Legislative, regulatory and administrative requirements of the European Union with which Australian-designated conformity assessment bodies will assess compliance	Legislative, regulatory and administrative requirements of Australia 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 and supplemented – Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended and supplemented – and any legislation adopted on the basis of these Directives.	– Therapeutic Goods Act 1989, as amended – Therapeutic Goods Regulations 1990, as amended – Therapeutic Goods (Medical Devices) Regulations 2002, as amended – and any subordinate legislation referred to in the above Acts or Regulations, as amended[8]

[8] General reference to Australia's subordinate legislation referred to in the Therapeutic Goods Act and Regulations and to anticipate any legislative changes.

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

Conformity Assessment Bodies designated by Australia to assess products against the European Union's legislative, regulatory and administrative requirements	Conformity Assessment Bodies designated by the European Union to assess products against Australia's legislative, regulatory and administrative requirements
The lists of designated Conformity Assessment Bodies have been mutually established by the Parties and will be maintained by them.	The lists of designated Conformity Assessment Bodies have been mutually established by the Parties and will be maintained by them.

SECTION III

AUTHORITIES RESPONSIBLE FOR DESIGNATING THE CONFORMITY ASSESSMENT BODIES FOR THE PURPOSES OF THIS AGREEMENT

For the conformity assessment bodies designated by Australia	For the conformity assessment bodies designated by the Member States of the European Union
— Department of Health and Ageing for the Therapeutic Goods Administration	— Belgium Ministère de la santé publique, de l'environnement et de l'intégration sociale/Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie — Denmark Sundhedsministeriet — Germany Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten — Greece Ministry of Health — Spain Ministerio de Sanidad y Consumo — France Agence française de sécurité sanitaire des produits de santé (AFSSAPS). — Ireland Department of Health — Italy Istituto superiore di sanità — Luxembourg Ministère de la santé — Netherlands Staat der Nederlanden

	— Austria Bundesministerium für Arbeit, Gesundheit und Soziales — Portugal Ministério da saúde — Finland Sosiaali- ja terveysministeriö/Social- och hälsovårdsministeriet — Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) — United Kingdom Medicines and Healthcare Products Regulatory Agency (MHRA) — Czech Republic Czech Office for Standards, Metrology and Testing

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

Procedures to be followed by Australia in designating Conformity Assessment Bodies to assess products against the European Union's requirements	Procedures to be followed by the European Union in designating Conformity Assessment Bodies to assess products against Australia's requirements
The Therapeutic Goods Administration of the Department of Health and Ageing will meet the requirements of the Directives listed in Section I, taking into account Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives and be designated for specific categories or classes of devices and conformity assessment procedures. For products covered by Section V, designation will occur on the basis of a confidence-building programme as mentioned in paragraph 1.2 of Section V.[9]	Conformity Assessment Bodies will meet the requirements mentioned in the Directives listed in Section I, taking into account Council Decision 93/465/EEC of 22 July 1993 concerning the modules for the various phases of the conformity assessment procedures and the rules for the affixing and use of the CE conformity marking, which are intended to be used in the technical harmonisation directives and be designated for specific categories or classes of devices and conformity assessment procedures. For products covered by Section V, designation will occur on the basis of a confidence-building programme as mentioned in paragraph 1.2 of Section V.[10]

SECTION V

ADDITIONAL PROVISIONS

1. Confidence building with respect to high-risk devices

1.1. 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;

– a medical device that is an implantable intra-ocular lens;

[9] Presumption of competence is following successful completion of confidence building for Section V devices.

[10] Presumption of competence is following successful completion of confidence building for Section V devices.

– a medical device that is an intra-ocular visco-elastic fluid;

– a medical device that is a barrier indicated for contraception or prevention of the sexual transmission of disease.

1.2. The Parties will establish a detailed programme to this effect involving the Therapeutic Goods Administration and the European Union's competent authorities.

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

1.4. Additional specific requirements for regulatory progress:

1.4.1. In pursuance of Articles 2, 7(1), 8(1) and 9(1) of the 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.

1.4.2. These specific requirements may include training, observed Conformity Assessment Body audits, visits and information and document exchange, including audit reports.

1.4.3. These requirements may likewise be applicable in relation to the designation of a Conformity Assessment Body in accordance with this Agreement.

2. Registration, listing and inclusion procedures for the Australian Register of Therapeutic Goods (ARTG)

2.1. The Parties recognise that Australian procedures under the Therapeutic Goods Act 1989 for the registration, listing or inclusion of products for market surveillance purposes, and corresponding European Union procedures, are unaffected by this Agreement.

2.2. Within the framework of this Agreement, the Australian Regulatory Authority will without delay enter a product from the European Union on the ARTG without further assessment of the product. This is contingent upon receipt of a product application accompanied by the prescribed fee and the Conformity Assessment Body's certification to Australia's requirements.

2.3. Any fees attached to registration by either Party will be related only to the costs of the medical device registration, enforcement and post-market surveillance activities of the Parties in this sector.

3. Exchange of information

The Parties agree to inform each other of:

– certificates withdrawn, suspended, restricted or revoked;

– adverse events in the context of the GHTF medical device vigilance procedure;

– matters concerning product safety; and

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

The Parties will establish contact points for each of these purposes.

The Parties will consider the consequences of the establishment of Eudamed.

In addition, the Therapeutic Goods Administration will advise of any certificates issued.

4. New legislation

The Parties jointly note that Australia is to introduce new legislation concerning in vitro diagnostics, and that any new arrangements will respect the principles on which the Agreement on Mutual Recognition is based.

The Parties mutually declare their plan to extend the scope of the MRA to IVDs as soon as the Australian legislation on IVDs is in place.

5. Measures to protect public health and safety

Implementation of this Sectoral Annex will not constrain a Party from taking measures necessary to protect public health and safety, in accordance with the legislation referred to in Section I. Each Party will duly inform the other Party of such measures.

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 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.

7. Divergence of views

Both Parties will use their best endeavours to resolve any divergence of views. Unresolved divergences of view will be referred to the Joint Sectoral Group.

APPENDIX 1

Pursuant to paragraph 2(a) of this Sectoral Annex, 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;

- a medical device that is 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 mutual 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.

This Agreement is drawn up in two originals in the Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovene, Spanish and Swedish languages, each text being equally authentic.

On behalf of Australia	On behalf of the European Union
Signed in Canberra on	Signed in Brussels on