AGREEMENT
ON MUTUAL RECOGNITION
IN RELATION TO CONFORMITY ASSESSMENT,
CERTIFICATES AND MARKINGS
BETWEEN THE EUROPEAN COMMUNITY
AND AUSTRALIA

THE EUROPEAN COMMUNITY and the GOVERNMENT OF AUSTRALIA, hereinafter referred to as "the Parties",

CONSIDERING the traditional links of friendship that exist between them,

CONSIDERING their shared commitment to promoting the enhancement of product quality, with a view to ensuring the health, safety and environment of their citizens,

DESIRING to conclude an agreement providing for the mutual recognition of the respective conformity assessment procedures required for market access to the territory of the Parties,

TAKING INTO ACCOUNT the improved conditions of trade between the Parties which the mutual recognition of test reports and certificates of conformity will bring about,

AWARE of the positive contribution that mutual recognition can have in encouraging greater international harmonization of standards and regulations,

NOTING the close relationship between Australia and New Zealand as confirmed in the Australian and New Zealand Closer Economic Relations Trade Agreement and the Trans-Tasman Mutual Recognition Arrangement as well as the growing level of integration of the Australian and New Zealand conformity assessment infrastructures through the Agreement concerning the establishment of the Council of the Joint Accreditation System of Australia and New Zealand (JAS-ANZ),

NOTING the close relationship between the European Community and Iceland, Liechtenstein and Norway through the Agreement on the European Economic Area, which makes it appropriate to consider the conclusion of a parallel mutual recognition agreement between Australia and these countries equivalent to this Agreement,

BEARING IN MIND their status as Contracting Parties to the Agreement establishing the World Trade Organization, and conscious in particular of their obligations under the World Trade Organization Agreement on Technical Barriers to Trade,

HAVE AGREED AS FOLLOWS:

ARTICLE 1

Definitions

1. General terms used in this Agreement and its Annexes shall have the meaning given in the definitions contained in ISO/IEC Guide 2 (1991) "General terms and their definitions concerning standardization and related activities" and in EN 45020 (1993 edition) unless the context requires otherwise. In addition, the following terms and definitions shall apply for the purpose of this Agreement:

"Conformity Assessment" means systematic examination to determine the extent to which a product, process or service fulfils specified requirements;

"Conformity Assessment Body" means a body whose activities and expertise include performance of all or any stage of the conformity assessment process;

"Designation" means the authorization by a Designating Authority of a Conformity Assessment Body to perform conformity assessment activities; "designated" has a corresponding meaning;

"Designating Authority" means a body with the legal power to designate, suspend or withdraw designation of Conformity Assessment Bodies under its jurisdiction.

2. The terms "Conformity Assessment Body" and "Designating Authority" apply mutatis mutandis to other bodies and authorities with corresponding functions referred to in some Sectoral Annexes.

ARTICLE 2

General obligations

1. The Government of Australia shall accept attestations of conformity including test reports, certificates, authorizations and marks of conformity as required by legislation and regulations identified in the Sectoral Annexes issued by designated Conformity Assessment Bodies in the European Community in accordance with this Agreement.

2. The European Community shall accept attestations of conformity including test reports, certificates, authorizations and marks of conformity as required by legislation and regulations identified in the Sectoral Annexes, issued by designated Conformity Assessment Bodies in Australia in accordance with this Agreement.

3. This Agreement shall not entail mutual acceptance of the standards or technical regulations of the Parties or mutual recognition of the equivalence of such standards or technical regulations.

ARTICLE 3

Sectoral coverage

1. This Agreement concerns the conformity assessment procedures to satisfy mandatory requirements covered by the Sectoral Annexes.

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 (Section I);

(c) a list of the designated Conformity Assessment Bodies (Section II);

(d) the Designating Authorities (Section III);

(e) a set of procedures for the designation of Conformity Assessment Bodies (Section IV), and

(f) additional provisions as required (Section V).

ARTICLE 4

Origin

1. This Agreement shall apply to products originating in the Parties to the Agreement according to the non-preferential rules of origin.

2. In case of conflicting rules, the non-preferential rules of the Party on whose territory the goods are marketed are determinative.

3. To the extent that the products referred to in paragraph 1 are also covered in a Sectoral Annex to the Agreement on Mutual Recognition in relation to conformity assessment between the European Community and New Zealand, this Agreement shall also apply to products of New Zealand origin.

4. To the extent that the products referred to in paragraph 1 are also covered in a Sectoral Annex to an Agreement on Mutual Recognition in relation to conformity assessment between Australia and States Contracting Parties to both the Convention of the European Free Trade Association (EFTA) and the Agreement on the European Economic Area (EEA), this Agreement shall also apply to products originating in any of these EFTA States.

ARTICLE 5

Conformity Assessment Bodies

In accordance with the terms of the Annex and the Sectoral Annexes, each Party recognizes that the Conformity Assessment Bodies designated by the other Party fulfil the conditions of eligibility to assess conformity in relation to their requirements as specified in the Sectoral Annexes. In designating such bodies, the Parties shall specify the scope of the conformity assessment activities for which they have been designated.

ARTICLE 6

Designating Authorities

1. The Parties shall ensure that the Designating Authorities responsible for designating the Conformity Assessment Bodies specified in the Sectoral Annexes shall have the necessary power and competence to designate, suspend, remove suspension and withdraw the designation of such bodies.

2. In making such designations 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.

3. In case of suspension of a designation or removal of such a suspension, the Designating Authority of the Party concerned shall immediately inform the other Party and the Joint Committee. Conformity assessment carried out by a suspended Conformity Assessment Body before its suspension shall remain valid unless otherwise determined by its Designating Authority.

ARTICLE 7

Verification of designation procedures

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

2. The Parties shall compare methods used to verify that the designated Conformity Assessment Bodies comply with the legislative, regulatory and administrative requirements outlined in the Sectoral Annexes and the competence requirements specified in the Annex. Existing systems for the accreditation of Conformity Assessment Bodies in the two Parties may be used for such comparison procedures.

3. Such comparison shall be carried out in accordance with the procedures to be determined by the Joint Committee established under Article 12.

ARTICLE 8

Verification of compliance
of Conformity Assessment Bodies

1. Each Party shall ensure that Conformity Assessment Bodies designated by a Designating Authority will be available for verification of their technical competence and compliance with other relevant requirements.

2. Each Party has the right to contest the technical competence and compliance of Conformity Assessment Bodies under the jurisdiction of the other Party. This right will be exercised under exceptional circumstances only.

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

4. Where the Joint Committee decides that verification of technical competence or compliance is required, it will be carried out in a timely manner jointly by the Parties with the participation of the relevant Designating Authorities.

5. The result of this verification will be discussed in the Joint Committee with a view to resolving the issue as soon as possible.

6. Except when decided otherwise by the Joint Committee, the contested Conformity Assessment Body, where it is included in Section II of a Sectoral Annex, shall be suspended by the competent Designating Authority from the time disagreement has been established in the Joint Committee until agreement has been reached in the Joint Committee on the status of that Body.

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.

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 where considerations of safety, health and environmental protection warrant more urgent action, notify the other Party of the new provisions at least 60 days before their entry into force.

ARTICLE 10

Uniformity of conformity assessment procedures

In the interests of promoting a uniform application of the conformity assessment procedures provided for in the laws and regulations of the Parties, the designated Conformity Assessment Bodies shall take part, as appropriate, in coordination and comparison exercises conducted by each of the Parties in the relevant areas covered by the Sectoral Annexes.

ARTICLE 11

Agreements with other countries

The Parties agree that mutual recognition agreements concluded by either Party with a country which is not a party to this Agreement shall in no way entail an obligation upon the other Party to accept test reports, certificates, authorizations and marks of conformity issued by Conformity Assessment Bodies in that third country, save where there is an express agreement between the Parties.

ARTICLE 12

Joint Committee

1. A Joint Committee made up of representatives of the two Parties shall be established. It is responsible for the effective functioning of the Agreement.

2. The Joint Committee shall determine its own rules of procedure. It shall take its decisions and adopt its recommendations by consensus. It can decide to delegate specific tasks to subcommittees.

3. The Joint Committee shall meet at least once a year unless it decides otherwise. If required for the effective functioning of this Agreement, and 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 to give effect to the decision by a Designating Authority to designate a particular Conformity Assessment Body;

(b) amending the Sectoral Annexes to give effect to the decision by a Designating Authority to withdraw designation of a particular Conformity Assessment Body;

(c) exchanging information concerning the procedures used by either Party to ensure that the Conformity Assessment Bodies specified in the Sectoral Annexes maintain the necessary level of competence;

(d) 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;

(e) 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;

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

(g) facilitating the extension of this Agreement to further sectors.

5. Any amendments to Sectoral Annexes made in accordance with the provisions of this Article shall be notified promptly in writing by the Chair of the Joint Committee to each Party.

6. The following procedure shall apply in relation to the inclusion in or withdrawal from a Sectoral Annex of a Conformity Assessment Body:

(a) a Party proposing an amendment to a Sectoral Annex to give effect to a decision by a Designating Authority to designate or withdraw designation of a Conformity Assessment Body shall forward its proposal to the other Party in writing, adding supporting documentation to the request;

(b) a copy of the proposal and documentation shall be sent to the Chair of the Joint Committee;

(c) in the event that the other Party consents to the proposal or upon the expiry of 60 days without an objection having been lodged, the inclusion in or withdrawal from the Sectoral Annex of the Conformity Assessment Body shall take effect, and

(d) 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 that Article.

7. In the event that a designated Conformity Assessment Body is withdrawn from a Sectoral Annex, conformity assessment carried out by that Conformity Assessment Body before the date of effect of its withdrawal shall remain valid unless otherwise determined by the Joint Committee. In the case of the inclusion of a new Conformity Assessment Body, conformity assessment carried out by such a Conformity Assessment Body shall be valid from the date the Parties agree to its inclusion in the Sectoral Annex.

8. Where a Party introduces new or additional conformity assessment procedures affecting a sector covered by a Sectoral Annex, the Joint Committee shall, unless the Parties agree otherwise, bring such procedures within the mutual recognition implementing arrangements established by this Agreement.

ARTICLE 13

Territorial application

This Agreement shall apply, on the one hand, to the territories in which the Treaty establishing the European Community is applied and under the conditions laid down in that Treaty and, on the other hand, to the territory of Australia.

ARTICLE 14

Entry into force and duration

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

2. Either Party may terminate this Agreement by giving the other Party six months' notice in writing.

ARTICLE 15

Final provisions

1. The Annex to this Agreement forms an integral part thereof.

2. Any amendment to this Agreement shall be done by mutual agreement.

3. The Parties shall conclude Sectoral Annexes, to which Article 2 applies, which will provide the implementing arrangements for this Agreement.

4. Amendments to the Sectoral Annexes shall be determined by the Parties through the Joint Committee.

5. This Agreement and the Sectoral Annexes are drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish and Swedish languages, each text being equally authentic.

ANNEX

PROCEDURES FOR THE DESIGNATION AND MONITORING OF CONFORMITY ASSESSMENT BODIES

A. General requirements and conditions

1. Designating Authorities shall only designate legally identifiable entities as Conformity Assessment Bodies.

2. Designating Authorities shall only designate Conformity Assessment Bodies able to demonstrate that they understand, have experience relevant to, and are competent to apply the conformity assessment requirements and procedures of the legislative, regulatory and administrative provisions of the other Party for which they are designated.

3. Demonstration of technical competence shall be based on:

   – technological knowledge of the relevant products, processes or services;

   – understanding of the technical standards and the general risk protection requirements for which designation is sought;

   – the experience relevant to the applicable legislative, regulatory and administrative provisions;

– the physical capability to perform the relevant conformity assessment activity;

– an adequate management of the conformity assessment activities concerned, and

– any other circumstance necessary to give assurance that the conformity assessment activity will be adequately performed on a continuous basis.

4. The technical competence criteria shall be based on internationally-accepted documents supplemented by specific interpretative documents developed as appropriate from time to time.

5. The Parties shall encourage harmonization of designation and conformity assessment procedures through cooperation between Designating Authorities and Conformity Assessment Bodies by means of coordination meetings, participation in mutual recognition arrangements, and working group meetings. Where accreditation bodies participate in the designation process they should be encouraged to participate in mutual recognition arrangements.

B. System to determine Conformity Assessment Bodies' competence

6. The Designating Authorities may apply the following processes to determine the technical competence of Conformity Assessment Bodies. If necessary, a Party will indicate to the Designating Authority the possible ways to demonstrate competence.

(a) Accreditation

Accreditation shall constitute a presumption of technical competence in relation to the requirements of the other Party when:

(i) the accreditation process is conducted in conformance with the relevant international documentation (EN 45000 series or ISO/IEC guides), and either

(ii) the accreditation body participates in mutual recognition arrangements where they are subject to peer evaluation which involves evaluation by individuals with recognized expertise in the field of the work being evaluated, of the competence of accreditation bodies and Conformity Assessment Bodies accredited by them, or

(iii) the accreditation bodies, operating under the authority of the Designating Authority, take part in accordance with procedures to be agreed in comparison programmes and exchanges of technical experience in order to ensure the continued confidence in the technical competence of the accreditation bodies and Conformity Assessment Bodies. Such programmes may include joint assessments, special cooperation programmes or peer evaluation.

When a Conformity Assessment Body is only accredited to evaluate a product, process or service for compliance with particular technical specifications, designation shall be limited to those technical specifications.

When a Conformity Assessment Body seeks designation to evaluate a particular product, process or service for compliance with essential requirements, the accreditation process shall incorporate elements which will permit assessment of the capability (technological knowledge and understanding of the generally stated risk protection requirements of the product, process or service or their use) of the Conformity Assessment Body to evaluate compliance with those essential requirements.

(b) Other means

When appropriate accreditation is not available or when special circumstances apply, the Designating Authorities shall require the Conformity Assessment Bodies to demonstrate their competence through other means such as:

– participation in regional/international mutual recognition arrangements or certification systems;

– regular peer evaluations;

– proficiency testing, and

– comparisons between Conformity Assessment Bodies.

C. Evaluation of the designation system

7. Once the designation systems to evaluate the competence of Conformity Assessment Bodies have been defined by each Party, the other Party may, in consultation with the Designating Authorities, check that the systems give sufficient assurance that the designation of the Conformity Assessment Bodies satisfies its requirements.

D. Formal designation

8. Designating Authorities shall consult the Conformity Assessment Bodies within their jurisdiction in order to determine their willingness to be designated under the terms of this Agreement. Such consultation should include those Conformity Assessment Bodies who do not operate under the respective legislative, regulatory and administrative requirements of their own Party but which may, nevertheless, be interested and capable of working to the legislative, regulatory and administrative requirements of the other Party.

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 included in or withdrawn from Section II of the Sectoral Annexes. 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.

10. When advising their Party's representative on the Joint Committee established under this Agreement, of the Conformity Assessment Bodies to be included in the Sectoral Annexes, 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;

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

(e) the conformity assessment procedures it is authorized to carry out, and

(f) the designation procedure used to determine competence.

E. Monitoring

11. Designating Authorities shall maintain, or cause to maintain, ongoing surveillance over designated Conformity Assessment Bodies by means of regular audit or assessment. The frequency and nature of such activities shall be consistent with international best practices or as agreed by the Joint Committee.

12. Designating Authorities shall require designated Conformity Assessment Bodies to participate in proficiency testing or other appropriate comparison exercises where such exercises are technically possible within reasonable cost.

13. Designating Authorities shall consult as necessary with their counterparts to ensure the maintenance of confidence in conformity assessment processes and procedures. This consultation may include joint participation in audits related to conformity assessment activities or other assessments of designated Conformity Assessment Bodies, where such participation is appropriate and technically possible within reasonable cost.

14. Designating Authorities shall consult, as necessary, with the relevant regulatory authorities of the other Party to ensure that all regulatory requirements are identified and are satisfactorily addressed.

SECTORAL ANNEX ON
MEDICINAL PRODUCTS GMP INSPECTION
AND BATCH CERTIFICATION
TO THE EUROPEAN COMMUNITY-AUSTRALIA AGREEMENT
ON MUTUAL RECOGNITION IN RELATION TO
CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

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

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

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

   "Medicinal products" means all products regulated by the pharmaceutical legislation in the European Community and Australia as listed in the Appendix to this Annex. 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 authorization 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 authorization holder or applicant and ensures that the medicinal product is made in compliance with this specification (Equivalent to Qualified Person certification in the European Community).

2. With respect to medicinal products covered by the legislation of one Party but not the other, the manufacturing company can request that, for the purpose of this Agreement, 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 agreed pre-marketing inspections. Operational arrangements are detailed under Section III, item 3b.

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 authorizations and for supervision of manufacturers of medicinal products shall certify that the manufacturer:

   – is appropriately authorized 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 recognized as equivalent by the two Parties, and which are listed in Appendix 1 to this Sectoral Annex. In case different GMP requirements are used as a reference (in line with the provisions in Section III, item 3b), this is to be mentioned in the certificate.

The certificates shall also identify the site(s) of manufacture (and contract testing laboratories, if any). The format of certificate is attached as Appendix 2; it may be modified by the Joint Committee, as established in Article 12 of the Agreement.

Certificates shall 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 shall 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 authorization. This certificate shall attest that the batch meets its specifications and shall 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 shall 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 shall contain a statement that the batch processing and packaging records were reviewed and found to be in conformity with GMP. The batch certificate shall be signed by the person responsible for releasing the batch for sale or supply, i.e. in the European Community the "qualified person" referred to in Article 21 of 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. In Australia, the responsible persons are for manufacturing quality control as specified in the Therapeutic Goods Regulation 19(b) under the Therapeutic Goods Act 1989.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

Subject to Section III "Operational provisions", general GMP inspections shall be carried out in accordance with the GMP requirements of the exporting Party. The legislative, regulatory and administrative requirements are listed in Appendix 1.

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

SECTION II

OFFICIAL INSPECTION SERVICES

For Australia:	Therapeutic Goods Administration (TGA) Department of Health and Family Services PO Box 100 Woden ACT 2606 Australia Tel.: 61-6-232-8632 Fax: 61-6-232-8659
For the European Community:	
BELGIUM	Inspection générale de la Pharmacie Algemene Farmaceutische Inspectie
DENMARK	Lægemiddelstyrelsen
GERMANY	Bundesministerium für Gesundheit
GREECE	Εθνικός Οργανισμός Φαρμάκου Ministry of Health and Welfare National Drug Organization (EOF)

SPAIN	For medicinal products for human use: Ministerio de Sanidad y Consumo Subdirección General de Control Farmacéutico For medicinal products for veterinary use: Ministerio de Agricultura, Pesca y Alimentación (MAPA) Dirrección General de la Producción Agraria
FRANCE	For medicinal products for human use: Agence du Médicament For veterinary medicinal products: CNEVA, Agence nationale du médicament vétérinaire, unité inspections For cosmetics: Ministre de l'emploi et de la solidarité Direction Générale de la Santé Sous direction pharmacie
IRELAND	Irish Medicines Board
ITALY	For medicinal products for human use: Ministero della Sanità Dipartimento Farmaci e Farmacovigilanza For medicinal products for veterinary use: Ministero della Sanità Dipartimento alimenti e nutrizione e sanità pubblica veterinaria – Div. IX

LUXEMBOURG	Division de la Pharmacie et des Médicaments
NETHERLANDS	Staat der Nederlanden
AUSTRIA	Bundesministerium für Arbeit, Gesundheit und Soziales
PORTUGAL –	For human and veterinary (non immunologicals): Instituto Nacional da Farmácia e do Medicamento INFARMED For veterinary immunologicals: Direcção-General de Veterinaria
FINLAND	Lääkelaitos/ Läkemedelsverket National Agency for Medicines
SWEDEN	Läkemedelsverket – Medical Products Agency
UNITED KINGDOM	For human and veterinary (non immunologicals): Medicines Control Agency For veterinary immunologicals: Veterinary Medicines Directorate
EUROPEAN COMMUNITY	Commission of the European Communities European Agency for the Evaluation of Medicinal Products (EMEA)

SECTION III

OPERATIONAL PROVISIONS

1. Transmission of inspection reports

Upon reasoned request, the relevant inspection services shall forward a copy of the last inspection report of the manufacturing site 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 item 2 below). Each Party shall 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 shall 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 shall be inspected in accordance with the applicable GMP of the exporting country (see Appendix 1).

(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 shall inspect in accordance with its own GMP or, in the absence of specific GMP requirements, in accordance with the applicable GMP of the importing country. 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) shall be determined according to a procedure established by the Joint Committee.

4. Nature of inspections

(a) Inspections shall 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 authorization. Where necessary, relevant product information (the quality dossier of an application/authorization dossier) shall 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 Agreement, except as provided for in paragraph 6 below.

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 the Agreement, the Parties shall exchange any information necessary for the mutual recognition of inspections.

In addition, the relevant authorities in Australia and in the European Community shall keep each other informed of any new technical guidance or inspection procedure. Each Party shall consult the other before their adoption and will endeavour to proceed towards their approximation.

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 shall 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 Community, the official batch release procedure for medicinal products for human use is specified in document "Administrative EC Batch Release Procedure III/3859/92" and different specific batch release procedures. 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, organized by the authorities, shall be accessible to inspectors of the other Party. The Parties to the Agreement will keep each other informed on these sessions.

10. Joint Inspections

In accordance with the general provisions of the Agreement, and by mutual agreement between the Parties, joint inspections may be authorized. These inspections are intended to develop common understanding and interpretation of practice and requirements. The setting up of these inspections and their form shall be agreed through procedures approved by the Joint Committee.

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 defect, 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 agreed.

The Parties shall ensure that any suspension or withdrawal (total or partial) of a manufacturing authorization, 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 Agreement, 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 Chief GMP Auditor
Therapeutic Goods Administration
Department of Health and Family Services
PO Box 100
Woden ACT 2606
Australia
Tel.: 61-6-232-8632
Fax: 61-6-232-8659

For medicinal products for use in animals:
The GMP Licensing Scheme Manager
National Registration Authority
PO Box E 240
Parkes ACT 2600
Australia
Tel.: 61-6-272-5158
Fax: 61-6-272-4753

For the European Community:

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. Divergence of views

Both Parties shall 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 Committee.

SECTION IV

TRANSITIONAL ARRANGEMENTS FOR VETERINARY MEDICINAL PRODUCTS

The Parties note that the current GMP requirements for veterinary medicinal products in Australia are not equivalent to those that apply in the European Community. Therefore, Australian veterinary medicinal products manufacturers will be inspected by Therapeutic Goods Administration (TGA) on behalf of the veterinary National Registration Authority, according to the TGA reference GMP and relevant additional EC GMP for veterinary medicinal products.

During a two-year transitional period, TGA inspection reports will be routinely sent to the importing Party, which may accept them or decide to carry out an inspection itself. If accepted, the European Community will recognize Australian manufacturers' certifications of batch conformity.

Two years after the entry into force of the Agreement, the European Community shall, subject to satisfactory verification of Australia's GMP inspection programme, recognize the conclusions of inspections carried out by the TGA and Australian manufacturers' certifications of batch conformity.

Should the National Registration Authority (NRA) 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 NRA GMP inspection programme.

Appendix 1

LIST OF APPLICABLE LEGISLATIVE, REGULATORY
AND ADMINISTRATIVE PROVISIONS

For the European Community:

Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to 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 (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization 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 (94/C63/03)

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

- Therapeutic Goods Act 1989
- Therapeutic Goods Regulations
- Therapeutic Goods (Charges) Act 1989
- Therapeutic Goods (Charges) Regulations

- Therapeutic Goods (Excluded Goods) Order No 1 of 1992
- Therapeutic Goods (Goods that are not Therapeutic Devices) Order No 1 of 1992
- Therapeutic Goods (Manufacturing Principles) Determinations

  Australian Code of Good Manufacturing Practice for Therapeutic Goods – Medicinal Products, August 1990, including:
  - Appendix A: Guidelines for Sterilization by Irradiation, October 1993
  - Appendix C: Guidelines on Tests for Sterility, July 1991
  - Appendix D: Guidelines for Laboratory Instrumentation, November 1991
  - Appendix E: Guidelines for Industrial Ethylene Oxide Sterilization of Therapeutic Goods, April 1986
  - Appendix F: Guidelines for Estimation of Microbial Count in Process Water, August 1990
  - Appendix G: Guidelines for Good Manufacturing Practice for Investigational Medicinal Products, June 1993
  - Australian Code of Good Manufacturing Practice – Blood and Blood products (including technical annexes 1-7), July 1992
- Australian Code of Good Manufacturing Practice for Therapeutic Goods – Sunscreen Products, February 1994
- Australian Code of Good Manufacturing Practice for Therapeutic Goods – Medicinal Gases, July 1992

and for products for veterinary use:

Legislation – Commonwealth:

- Agricultural and Veterinary Chemicals (Administration) Act, 1992
- Agricultural and Veterinary Chemicals Act, 1993
- Agricultural and Veterinary Chemicals Code Act, 1993
- Agricultural and Veterinary Chemicals (Consequential Amendments) Act, 1993

Legislation – New South Wales:

- Stock Foods and Medicines Act, 1940
- Public Health Act, 1961
- Poison Act, 1966
- Pesticides and Allied Chemicals Act, 1979

Legislation – Victoria:

- Animal Preparations Act, 1987
- Health Act, 1958
- Drugs, Poisons and Controlled Substances Act, 1981

Legislation – Queensland:

- Agricultural Standards Act, 1952-1981
- Stock Act, 1915-1976
- Health Act, 1937-1987

Legislation – South Australia:

- Stock Medicines Act, 1939-1978
- Stock Foods Act, 1941
- Dangerous Drugs Act, 1986
- Controlled Substances Act, 1984
- Stock Diseases Act, 1934

Legislation – Western Australia:

- Veterinary Preparations and Animal Feeding Stuffs Act, 1976–1982
- Poisons Act, 1964-1981
- Health (Pesticides) regulations, 1956

Legislation – Tasmania:

- Veterinary Medicines Act, 1987
- Poisons Act, 1971
- Public Health Act, 1962
- Pesticides Act, 1968

Legislation – Northern Territory:

- Poisons and Dangerous Drugs Act, 1983
- Therapeutic Goods and Cosmetics Act, 1986
- Stock Diseases Act, 1954

Appendix 2

CERTIFICATE OF PHARMACEUTICAL MANUFACTURER IN THE FRAMEWORK OF THE AGREEMENT ON MUTUAL RECOGNITION IN RELATION TO CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS BETWEEN AUSTRALIA AND THE EUROPEAN COMMUNITY, SECTORAL ANNEX ON MEDICINAL PRODUCTS GMP INSPECTION AND BATCH CERTIFICATION

As requested by the Competent Authorities of Australia / .....
(*) on ...../...../..... (date) (reference: .....), the Competent Authority of ..... confirms the following:

The company .....
whose legally registered address is: .....
.....
.....
has been authorized, under the Therapeutic Goods Act 1989 / Directive 75/319/EEC, Article 16, and Directive 81/851/EEC, Article 24, transposed in the national legislation of ..... (*), under the authorization reference number .....
covering the following site(s) of manufacture (and contract testing laboratories, if any):
1 .....
.....
2 .....
.....
3 .....
.....
to carry out the following manufacturing operations:

+ complete manufacture (**)

+ partial manufacture (**), i.e. (detail of manufacturing operations authorized):
.....
.....
for the following medicinal product: .....

for human use / use in animals (**).

From the knowledge gained during inspections of this manufacturer, the latest of which was conducted on ..../..../.... (date), it is considered that the company complies with the Good Manufacturing Practice requirements referred to in the Agreement on Mutual Recognition in relation to Conformity Assessment, Certificates and Markings between Australia and the European Community.

..../..../.... (date) For the Competent Authority,

(Name and signature of the officer responsible)

(*) : insert European Community Member State or European Community as required
(**) : delete that which does not apply

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 provisions of this Sectoral Annex shall apply to the following products:

Products for export to the European Community	Products for export to Australia
• All medical devices subject to third party conformity assessment procedures, both product related and quality system related, 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 and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, but excluding the following products: • radioactive materials to the extent these may be considered medical devices, and • medical devices incorporating tissues of animal origin. However, medical devices: (a) incorporating refined derivatives of animal-derived waxes, heparin and gelatine which conform to pharmacopoeial standards and sintered hydroxyapatite, or (b) incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only, shall be included within the scope of this Sectoral Annex.	• All medical devices subject under the Australian Therapeutic Goods Act 1989 and Therapeutic Goods Regulations, to third party conformity assessment procedures, both product related and quality systems related, apply, but excluding the following products: • radioactive materials to the extent these may be considered medical devices, and • medical devices incorporating tissues of animal origin. However, medical devices (a) incorporating refined derivatives of animal-derived waxes, heparin and gelatine which conform to pharmacopoeial standards and sintered hydroxyapatite, or (b) incorporating tissues of animal origin and where the device is intended to come into contact with intact skin only, shall be included within the scope of this Sectoral Annex.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia with which European Community designated Conformity Assessment Bodies shall 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 • Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as amended	• Therapeutic Goods Act 1989 • Therapeutic Goods (Charges) Act 1989 • Therapeutic Goods Regulations • Therapeutic Goods (Charges) Regulations • Therapeutic Goods (Excluded Goods) Order No 1 of 1992 • Therapeutic Goods (Goods that are not therapeutic devices) Order No 1 of 1992 • Therapeutic Goods (Manufacturing Principles) Determinations – European Standard EN 46001: 1993, specification for Application of EN 29001 (BS 5750: Part 1) to the manufacture of medical devices

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess products against the European Community's legislative, regulatory and administrative requirements	The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrative requirements
The Therapeutic Goods Administration of the Department of Health and Family Services, in respect of the conformity assessment procedures required under the Community legislation cited in Section I, for all medical devices and for all modules for the various phases of the conformity assessment procedures applicable to such devices	The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Further names to be added as required]

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING
THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
• Department of Health and Family Services	• Belgium Ministère de la Santé publique, de l'Environnement et de l'Intégration sociale Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie • Denmark Sundhedsministeriet • Germany Bundesministerium für Gesundheit • Greece Υπουργείο Υγείας και Πρόνοιας Ministry of Health • Spain Ministerio de Sanidad y Consumo • France Ministère de l'emploi et de la solidarité Direction des hôpitaux Bureau des dispositifs médicaux Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation • Ireland Department of Health • Italy Ministero della Sanità

	• Luxembourg Ministère de la Santé • Netherlands Staat der Nederlanden • Austria Bundesministerium für Arbeit, Gesundheit und Soziales • Portugal Ministerio da Saude • 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 Department of Health

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess products against Australia's requirements
The Conformity Assessment Bodies listed in Section II must 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 harmonization directives and be designated on the basis of the procedures defined in the Annex to the Agreement. This may be demonstrated through: • Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guides 28 and 40. • Quality System Certification Bodies operating according to the requirements of EN 45012 or ISO Guide 62. • Inspection Bodies operating according to the requirements of EN 45004 or ISO Guide 39.	Conformity Assessment Bodies will be designated in accordance with the procedures set out in the Annex to the Agreement. Conformity Assessment Bodies which are Notified Bodies under Annex XI of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices or Annex VIII of 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 in conjunction with 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 harmonization directives shall be presumed competent to carry out conformity assessment to Australian requirements for those devices and procedures for which they have been correspondingly notified by their competent authorities in Europe.

SECTION V

ADDITIONAL PROVISIONS

1. Transitional period for certain high-risk devices

1.1. A transitional period, for the purpose of strengthening confidence in the designating systems of each of the Parties will apply for the Medical Devices specified in Schedule 3 of the Therapeutic Goods Regulation and Medical Devices Directives (90/385/EEC and 93/42/EEC) and listed below:

- active implantable devices,
- intra-uterine contraceptive devices,
- heart valves,
- intra-ocular lenses,
- intra-ocular visco elastic fluids,
- powered drug infusion pumps,
- implantable breast prostheses (other than those containing only saline or water),
- barrier contraceptive devices (excluding condoms),
- instrument grade disinfectants.

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

1.3. This confidence-building period will be completed within 18 months from the date of entry into force of the Agreement.

2. Medical devices incorporating medicinal substances

2.1. In order to meet European Community requirements, the following procedures shall apply to medical devices incorporating medicinal substances referred to in Article 1(4) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices:

(a) if a medical device incorporates a substance with ancillary medicinal action and which is already established by monographs of the European Pharmacopoeia, the consultation required under Annex II or III to Council Directive 93/42/EEC of 14 June 1993 concerning medical devices will be carried out with the Australian competent authority;

(b) if a medical device incorporates a substance with ancillary medicinal action other than one specified in the European Pharmacopoeia, the Therapeutic Goods Administration shall carry out such consultation with one of the competent authorities within the European Community responsible for authorizing the placing on the market of medicinal products.

2.2. In order to meet Australian requirements, the following procedures shall apply to medical devices incorporating medicinal substances referred to in Article 1(4) of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices:

(a) if a medical device incorporates a substance with ancillary medicinal action and which is already established by monographs of the European Pharmacopoeia, the consultation required under Annex II or III of Council Directive 92/42/EEC of 14 June 1993 concerning medical devices will be carried out with the European Community's competent authority;

(b) if a medical device incorporates a substance with ancillary medicinal action other than one specified in the European Pharmacopoeia, consultation shall take place with the Department of Health and Family Services before taking a decision.

3. Registration and listing procedures

3.1. The Parties recognize that Australian procedures under the Therapeutic Goods Act for the registration or listing of products for market surveillance purposes, and corresponding European Community procedures, are unaffected by this Agreement.

3.2. Within the framework of this Agreement, the Australian Regulatory Authority will within five (5) working days register a product from the European Community upon receipt of an application accompanied by the designated fee without further assessment of the product.

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

4. Exchange of information

The Parties agree to inform each other of incidents in the context of medical device vigilance procedure, or with regard to matters concerning product safety, and shall establish contact points for this purpose.

5. In order to facilitate the application of this Sectoral Annex, the Parties will establish a guidance document setting out the procedures and requirements which are equivalent under the legislation of the two Parties, as well as modalities to facilitate registration requirements.

6. New legislation

The Parties note the possibility of Australia introducing new legislation concerning medical devices, and agree that any new arrangements will respect the principles on which the Mutual Recognition Agreement is based, notably Article 2 of the Agreement.

7. Divergence of views

Both Parties shall use their best endeavours to resolve any divergence of views concerning compliance of manufacturers and conclusions of conformity assessment reports. Unresolved divergencies of view will be referred to the Joint Committee.

SECTORAL ANNEX ON
TELECOMMUNICATIONS TERMINAL EQUIPMENT
TO THE EUROPEAN COMMUNITY-AUSTRALIA AGREEMENT
ON MUTUAL RECOGNITION IN RELATION TO
CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

The provisions of this Sectoral Annex shall apply to the following:

Products for export to the European Community	Products for export to Australia
Any product falling under the scope of Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity. In general terms, that Council Directive covers: (a) terminal equipment intended to be connected to the public telecommunications networks. The terminal equipment may be connected directly or indirectly to the termination of the public telecommunications network, and (b) satellite earth station equipment, which is capable of being used either for transmission only, or for transmission and reception, or for reception only, of radio communications signals by means of satellites or other space-based systems. Purpose-built satellite earth station equipment used as part of the public switched telecommunications network is excluded. This list of product groups may be extended to include other European Community common technical regulations in this sector as they become available.	Any product defined as customer equipment in the Telecommunications Act 1997. In general this is equipment whose parameters are defined in the Australian Communications Authority Technical Standards as determined under the above Act. These requirements are set out in the Telecommunications Labelling (Customer Equipment and Customer Cabling) Notice No 2 of 1997.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia with which European Community designated Conformity Assessment Bodies shall assess compliance
• Directive 98/13/EC of the European Parliament and of the Council of 12 February 1998 relating to telecommunications terminal equipment and satellite earth station equipment, including the mutual recognition of their conformity. • Commission Decision 95/290/EC of 17 July 1995 on a common technical regulation for public land-based European radio message system (ERMES) receiver requirement • Commission Decision 95/525/EC of 28 November 1995 on a common technical regulation for attachment requirements for terminal equipment for digital European cordless telecommunications (DECT), public access profile (PAP) applications • Commission Decision 96/629/EC of 23 October 1996 on a common technical regulation for telephony application requirements for public pan-European cellular digital land-based mobile communications, Phase II	• Telecommunications Act 1997 • Radiocommunications Act 1992

• Commission Decision 96/630/EC of 23 October 1996 on a common technical regulation for the general attachment requirements for public pan-European cellular digital land-based mobile communications, Phase II • Commission Decision 97/346/EC of 20 May 1997 on a common technical regulation for the pan-European integrated services digital network (ISDN) basic access • Commission Decision 97/347/EC of 20 May 1997 on a common technical regulation for the pan-European integrated services digital network (ISDN) primary rate access • Commission Decision 97/486/EC of 9 July 1997 on a common technical regulation for the general attachment requirements for terminal equipment to interface to open network provision (ONP) two-wire analogue leased lines • Commission Decision 97/487/EC of 9 July 1997 on a common technical regulation for the attachment requirements for terminal equipment to interface to open network provision (ONP) four-wire analogue leased lines • Commission Decision 97/520/EC of 9 July 1997 on a common technical regulation for the attachement requirements for the terminal equipment interface for connection to 2048 kbit/s digital unstructured ONP leased lines (Amendment 1) • Commission Decision 97/521/EC of 9 July 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 2048 kbit/s digital structured ONP leased lines	

• Commission Decision 97/522/EC of 9 July 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 64 kbit/s digital unrestricted ONP leased lines (Amendment 1) • Commission Decision 97/523/EC of 9 July 1997 on a common technical regulation for the general terminal attachment requirements for digital enhanced cordless telecommunications (DECT) (edition 2) • Commission Decision 97/524/EC of 9 July 1997 on a common technical regulation for the telephony application requirements for digital enhanced cordless telecommunications (DECT) (edition 2) • Commission Decision 97/525/EC of 9 July 1997 on a common technical regulation for the attachment requirements for terminal equipment for digital enhanced cordless telecommunications (DECT) generic access profile (GAP) applications • Commission Decision 97/526/EC of 9 July 1997 on a common technical regulation for the general attachment requirements for public pan-European cellular digital land-based mobile communications (edition 2) • Commission Decision 97/527/EC of 9 July 1997 on a common technical regulation for the telephony application requirements for public pan-European cellular digital land-based mobile communications (edition 2)	

• Commission Decision 97/528/EC of 9 July 1997 on a common technical regulation for the general attachment requirements for mobile stations intended to be used with Phase II public digital cellular telecommunications networks operating in the DCS 1800 band • Commission Decision 97/529/EC of 9 July 1997 on a common technical regulation for the telephony application requirements for mobile stations intended to be used with Phase II public digital cellular telecommunications networks operating in the DCS 1800 band • Commission Decision 97/544/EC of 9 July 1997 on a common technical regulation for terminal equipment to be connected to public circuit switched data networks and ONP leased circuits using a CCITT Recommendation X.21 type interface • Commission Decision 97/545/EC of 9 July 1997 on a common technical regulation for the general attachment requirements for data terminal equipment (DTE) to connect to packet switched public data networks (PSPDNs) offering CCITT Recommendation X.25 interfaces • Commission Decision 97/639/EC of 19 September 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 34 Mbit/s digital unstructured and structured leased lines • Commission Decision 97/751/EC of 31 October 1997 on a common technical regulation for the attachment requirements for the terminal equipment interface for connection to 140 Mbit/s digital unstructured and structured leased lines	

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess products against the European Community's legislative, regulatory and administrative requirements	The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrative requirements
The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Note: Further names to be added as required]	The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Note: Further names to be added as required]

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING
THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
Under the authority of the Government of Australia: (a) For Certification Bodies: • The Joint Accreditation System of Australia and New Zealand (JAS-ANZ), and (b) For Testing Laboratories and Inspection Bodies: • The National Association of Testing Authorities, Australia (NATA).	• Belgium Institut belge des services postaux et des télécommunications Belgisch instituut voor postdiensten en telecommunicatie • Denmark Telestyrelsen • Germany Bundesministerium für Wirtschaft • Greece Υπουργείο Μεταφορών και Επικοινωνιών Ministry of Transport and Communications • Spain Ministerio de Fomento • France Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction des postes et télécommunications Service des télécommunications Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation • Ireland Department of Transport, Energy and Communications

	• Italy Ispettorato Generale TLC • Luxembourg Administration des Postes et Télécommunications • Netherlands De Minister van Verkeer en Waterstaat • Austria Bundesministerium fur Wissenschaft und Verkehr • Portugal Instituto das Comunicações de Portugal • Finland Liikenneministeriö/Trafikministeriet Telehallintokeskus/ Teleförvaltningscentralen • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • UK Department of Trade and Industry

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess products against Australia's requirements
The Conformity Assessment Bodies listed in Section II 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 harmonization directives and be designated on the basis of the procedures defined in the Annex to the 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 JAS-ANZ, or • able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	The procedures for designating Conformity Assessment Bodies will be consistent with the principles and procedures set out in the Annex to the Agreement. (a) Testing Laboratories: The following procedures are deemed to be consistent with those set out in the Annex to the Agreement: • accreditation by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing, or • ability to demonstrate competence under an equivalent accreditation scheme.

(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 the Agreement. (c) Testing laboratories operating according to the requirements of EN 45001 or ISO Guide 25, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	(b) Certification Bodies: The following procedures are deemed to be consistent with those set out in the Annex to the Agreement: • accreditation by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification; • accreditation by an accreditation body with which JAS-ANZ has a mutual recognition agreement, or • ability to demonstrate competence under an equivalent accreditation scheme.

SECTION V

ADDITIONAL PROVISIONS

1. In accordance with Part 21 of the Telecommunications Act 1997, the Australian Communications Authority (ACA) is required to authorize a manufacturer or importer to apply a label to customer equipment prior to placing that customer equipment on the Australian market.

   Within the framework of this Agreement, the ACA will use its best endeavours, within five (5) working days and in any case no longer than 10 days, to issue such an authorization in accordance with procedures set out in the Telecommunications Labelling (Customer Equipment and Customer Cabling) Notice No 2 of 1997.

2. It is agreed by both Parties that the relevant Council Directives and Australian legislative and regulatory requirements allow mutual recognition of separate elements of the conformity assessment process. Accordingly each Party shall accept test reports issued by Conformity Assessment Bodies designated by the other Party as meeting its requirements in this regard.

3. Where the legislative, regulatory or administrative provisions of either Party require it, Conformity Assessment Bodies subcontracting all or part of the testing must subcontract only to Testing Laboratories accredited in accordance with clause (a) in Section IV above.

4. In respect of telecommunications terminal equipment which is subject to the provisions of Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, the relevant provisions of the Sectoral Annexes on, respectively, Low Voltage Equipment and Electromagnetic Compatibility shall apply.

ACA TECHNICAL STANDARDS

TS 001	TS 014
TS 002	TS 015
TS 003	TS 016
TS 004	TS 018
TS 005	TS 019
TS 006	TS 020
TS 007	TS 021.1
TS 008	TS 021.2
TS 009	TS 021.3
TS 012	TS 023
TS 013.1	TS 024
TS 013.2	TS 028

SECTORAL ANNEX ON
LOW VOLTAGE EQUIPMENT
TO THE EUROPEAN COMMUNITY-AUSTRALIA AGREEMENT
ON MUTUAL RECOGNITION IN RELATION TO
CONFORMITY ASSESSMENT, CERTIFICATES AND MARKINGS

SCOPE AND COVERAGE

The provisions of this Sectoral Annex shall apply to the following types of low voltage equipment:

- All products falling within the scope of Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits.

- Electrical products which are within the scope of Australian State and Territory legislation for the safety of low voltage electrical equipment.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia with which European Community designated Conformity Assessment Bodies shall assess compliance
Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, as amended	New South Wales • Electricity Act 1945 • Electricity (Equipment Safety) Regulation 1994 Victoria • State Electricity Commission Act 1958 • Electricity Industry Act 1993 Queensland • Electricity Act 1994 • Electricity Regulation 1994 Western Australia • Electricity Act 1945 • Electricity Act Regulations 1947 South Australia • Electrical Products Act 1988 Tasmania • Hydro Electric Commission Act 1944 Australian Capital Territory • Electricity Act 1971 Northern Territory • Power and Water Authority Act 1987 • Electricity By-Laws

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess products against the European Community's legislative, regulatory and administrative requirements	The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrative requirements
The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Note: Further names to be added as required]	The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Note: Further names to be added as required]

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING
THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
Under the authority of the Government of Australia: (a) For Certification Bodies: • The Joint Accreditation System of Australia and New Zealand (JAS-ANZ), and (b) For Testing Laboratories and Inspection Bodies: • The National Association of Testing Authorities, Australia (NATA)	• Belgium Ministère des affaires économiques Ministerie van Economische Zaken • Denmark Boligministeriet • Germany Bundesministerium für Arbeit und Sozialordnung • Greece Υπουργείο Ανάπτυξης Ministry of Development • Spain Ministerio de Industria y Energía • France Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation • Ireland Department of Enterprise and Employment • Italy Ministero dell' Industria, del Commercio e dell' Artigianato • Luxembourg Ministère des transports

	• Netherlands Staat der Nederlanden • Austria Bundesministerium für Wirtschaftliche Angelegenheiten • Portugal Under the authority of the Government of Portugal: Instituto Português da Qualidade • Finland Kauppa- ja teollisuusministeriö / Handels- och industriministeriet • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • UK Department of Trade and Industry

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess products against Australia's requirements
The Conformity Assessment Bodies listed in Section II 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 harmonization directives and be designated on the basis of the procedures defined in the Annex to the Agreement. This may be demonstrated through: (a) Inspection Bodies operating in accordance with the requirements of EN 45004 or ISO Guide 39, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. (b) Testing laboratories operating according to the requirements of EN 45001 or ISO Guide 25, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	The following procedures are deemed to be consistent with the procedures set out in the Annex to the Agreement: (a) Testing Laboratories: • accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing, or • recognized within the IECEE CB Scheme, or • able to demonstrate competence under an equivalent accreditation scheme. (b) Certification Bodies • accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification • membership of the IECEE CB Scheme • accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement, or • able to demonstrate competence under an equivalent accreditation scheme.

SECTION V

ADDITIONAL PROVISIONS

1. In accordance with Australian legislation set out in Section I of this Annex, certain types of electrical equipment (the Declared Articles list) are required to be registered before they can be placed on the market.

   Within the framework of this Agreement, the Australian State and Territory Regulatory Authorities will within five (5) working days register a product from the European Community upon receipt of an application accompanied by the designated fee without further assessment of the product.

   The designated fee will be related to the costs of the electrical equipment registration, enforcement and post-market surveillance activities of the Australian regulatory authorities.

2. The Parties note that a Regulatory Compliance Mark (RCM) is to be introduced in Australia in August 1996. The adoption of the RCM, together with changes to Australian regulatory requirements, may result in due course in the removal of the arrangements described in paragraph 1 above. Any conditions for use of the RCM will respect the principles of the Mutual Recognition Agreement, notably Article 2 of the Agreement.

3. Where the legislative, regulatory or administrative provisions of either Party require it, Conformity Assessment Bodies subcontracting all or part of the testing must subcontract only to Testing Laboratories accredited in accordance with clause (a) in Section IV above.

4. In the event of a challenge within the European Community under Article 8(2) of Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits, test reports issued by designated Conformity Assessment Bodies in Australia will be accepted by European Community authorities in the same way that reports from European Community Notified Bodies are accepted. That is, Conformity Assessment Bodies in Australia will be recognized under Article 11 of that Council Directive as "bodies which may make a report in accordance with Article 8".

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

SCOPE AND COVERAGE

The provisions of this Sectoral Annex shall apply to the following:

- Electromagnetic compatibility of equipment as defined in Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, but excluding radiocommunications equipment which is not connected to the public switched telecommunication networks, and

- Electromagnetic compatibility of equipment regulated under the Australian Radiocommunications Act 1992.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia with which European Community designated Conformity Assessment Bodies shall assess compliance
Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, as amended	• Radiocommunications Act 1992

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess products against the European Community's legislative, regulatory and administrative requirements	The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrative requirements
The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Further names to be added as required]	The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Further names to be added as required]

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING
THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
Under the authority of the Government of Australia: (a) For Certification Bodies: • The Joint Accreditation System of Australia and New Zealand (JAS-ANZ) (b) For Testing Laboratories and Inspection Bodies: • The National Association of Testing Authorities, Australia (NATA)	• Belgium Ministère des Affaires Economiques Ministerie van Economische Zaken • Denmark For telecommunication equipment: Telestyrelsen For other equipment: Danmarks Elektriske Materielkontrol (DEMKO) • Germany Bundesministerium für Wirtschaft • Greece Υπουργειο Μεταφορών καί Επικοινωνιών Ministry of Transport and Communications • Spain For telecommunications equipment: Ministerio de Fomento for other equipment: Ministerio de Industria y Energía • France Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation • Ireland Department of Transport, Energy and Communications

	• Italy Ministero dell' Industria, del Commercio e dell' Artigianato • Luxembourg Ministère des Transports • Netherlands De Minister van Verkeer en Waterstaat • Austria For telecommunication equipment: Bundesministerium für Wissenschaft und Verkehr For other equipment: Bundesministerium für wirtschaftliche Angelegenheiten • Portugal Under the authority of the Government of Portugal: Instituto das Comunicações de Portugal • Finland For telecommunication equipment: Liikennneministeriö/Trafikministeriet For other equipment: Kauppa- ja teollisuusministeriö/ Handels- och industriministeriet • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • UK Department of Trade and Industry

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess products against Australia's requirements
The Conformity Assessment Bodies listed in Section II 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 harmonization directives, and are designated on the basis of the procedures defined in the Annex to the Agreement. This may be demonstrated through: (a) For the purposes of Article 10(5) of Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, Inspection Bodies operating according to the requirements of EN 45004 or ISO Guide 39, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	The following procedures are deemed to be consistent with the procedures set out in the Annex to the Agreement: (a) Testing Laboratories operating according to the requirements of ISO Guide 25 or EN 45001, and either: • accredited by accreditation bodies which are signatories to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing, or • able to demonstrate competence under an equivalent accreditation scheme. (b) Inspection Bodies operating according to the requirements of ISO Guide 39 or EN 45004, and either: • accredited by accreditation bodies which are signatories to a European Multilateral Agreement, or • able to demonstrate competence under an equivalent accreditation scheme.

(b) For Competent Bodies according to Article 10(2) of Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, Testing Laboratories operating according to the requirements of EN 45001 or ISO Guide 25, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	

SECTION V

ADDITIONAL PROVISIONS

The European Community and Australia agree that

1. Reports and certificates prepared by European Community competent bodies will be accepted by Australian regulatory authorities, and

2. Reports and certificates prepared by designated Conformity Assessment Bodies in Australia will also be accepted by European Community authorities on the same basis as reports and certificates prepared by European Community competent bodies.

3. Where the legislative, regulatory or administrative provisions in either Party require it, Conformity Assessment Bodies subcontracting all or part of the testing must subcontract only to testing laboratories accredited in accordance with clause (a) in Section IV above.

4. The Parties note the Australian requirement for its Competent Bodies to be members of the Australian Association of Competent Bodies and the Commission's current consideration of a proposal to establish a Technical Secretariat for Notified Bodies and Competent Bodies under Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility to promote the coordination activities of these Bodies under this Directive.

   The Parties also note the European Commission's intention to encourage Competent Bodies to participate in coordination activities.

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

SCOPE AND COVERAGE

The provisions of this Sectoral Annex shall apply to the products listed in Annex IV of Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery and to tower cranes and mobile cranes.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia with which European Community designated Conformity Assessment Bodies shall assess compliance
• Council Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery, as amended • Directives setting out noise limitation requirements for tower cranes as follows: – Council Directive 79/113/EEC of 19 December 1978 on the approximation of the laws of the Member States relating to the determination of the noise emission of construction plant and equipment, as amended	The following legislative, regulatory and administrative requirements cover the conformity assessment procedures for the use of products covered by this Annex. New South Wales Victoria • Occupational Health and Safety Act 1985 ([1]) • Occupational Health and Safety (Plant) Regulations 1995 ([1]) • Code of Practice for Plant 1995 ([1]) • Equipment (Public Safety) Act 1994 ([1]) • Equipment (Public Safety) (General) Regulations 1995 ([1])

– Council Directive 84/532/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to common provisions for construction plant and equipment, as amended – Council Directive 84/534/EEC of 17 September 1984 on the approximation of the laws of the Member States relating to the permissible sound power level of tower cranes, as amended	Queensland • Workplace Health & Safety Act 1995 • Workplace Health & Safety Regulation 1995 • Workplace Health & Safety (Plant) Code of Practical Approval Notice 1993 Western Australia • Occupational Safety & Health Regulations 1996 South Australia • Occupational Health, Safety & Welfare Act 1986 • Occupational Health, Safety & Welfare Regulations 1995 Tasmania • Workplace Health & Safety Act 1995 Australian Capital Territory Northern Territory • Work Health Act • Work Health (Occupational Health and Safety) Regulations ([1]) There are no mandatory conformity assessment requirements under this legislation.

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess products against the European Community's legislative, regulatory and administrative requirements	The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrativerequirements
The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Further names and details to be added as required]	The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Further names and details to be added as required]

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING
THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Commission
Under the authority of the Government of Australia: (a) For Certification Bodies: • the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) (b) For Testing Laboratories and Inspection Bodies: • The National Association of Testing Authorities, Australia (NATA)	• Belgium Ministère de l'Economiel Ministerie van Economie • Denmark Direktoratet for Arbejdstilsynet • Germany Bundesministerium für Arbeit und Sozialordnung • Greece Υπουργείο Ανάπτυξης Ministry of Development • Spain Ministerio de Industria y Energía • France Ministère de l'emploi et de la solidarité Direction des relations du travail Bureau CT5 Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation • Ireland Department of Enterprise and Employment

	• Italy Ministero dell' Industria, del Commercio e dell' Artigianato • Luxembourg Ministère des transports • Netherlands Staat der Nederlanden • Austria Bundesministerium für wirtschaftliche Angelegenheiten • Portugal Under the authority of the Government of Portugal: Instituto Português da Qualidade • Finland Sosiaali- ja terveysministeriö/ Social- och hälsovårdsministeriet • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • UK Department of Trade and Industry

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess products against Australia's requirements
The Conformity Assessment Bodies listed in Section II 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 harmonization directives, and are designated on the basis of the procedures defined in the Annex to the Agreement. This may be demonstrated through: (a) For the purpose of Directive 89/392/EEC of 14 June 1989 on the approximation of the laws of the Member States relating to machinery: Inspection Bodies operating to the requirements of EN 45004 or ISO Guide 39, and either: • accredited by NATA, or • able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	In accordance with the specific requirements set out in the legislation, regulations and administrative provisions listed in Section I, and where these make compliance with Australian standards for plant mandatory, the Conformity Assessment Bodies listed in Section II are designated by the Designating Authorities specified in Section III in accordance with the following criteria: • Design Verification for compliance with technical standards may not be required under all legislation listed in Section I. • If design verification is required it must be conducted by a design verifier who has not been involved in the machinery design and who has acquired through training, qualification, or experience, or a combination of these, the knowledge and skills enabling that person to perform this task.

(b) For the purpose of Council Directives setting out noise limitation requirements for tower cranes: Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guides 28 and 40, 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 the Agreement.	Where the designer and design verifier are employed or engaged by the same person the whole of the design process must, if the legislation requires, operate: (a) within a quality system meeting requirements of ISO 9001 and be certified by a Quality Systems Certification Body operating according to the requirements of ISO Guide 62 or EN 45012, and either: • accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification, or • accredited by an accreditation body with which JAS-ANZ has a mutual recognition agreement, and (b) in conformity with EN 45004 or ISO Guide 39 and accredited by an accreditation body meeting the requirements of ISO Guide 58 or EN 45002/3. For Victoria there are no mandatory conformity assessment requirements under the legislation listed in Section I other than that the design must be verified by someone who did not participate in the design of the plant subject to design verification.

SECTION V

ADDITIONAL PROVISIONS

1. In respect of machinery which is subject to the provisions of Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, the relevant provisions of the Sectoral Annexes on, respectively, Low Voltage Equipment and Electromagnetic Compatibility shall apply.

2. Upon the date of application of the provisions of the Directive of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous and particulate pollutants from internal combustion engines to be installed in non-road mobile machinery, at present European Commission proposal COM(95) 350, bodies in Australia which have been designated to issue type approvals according to this Directive shall, either directly or through the authority responsible for their designation, fulfil the notification and other obligations placed upon approval authorities under the relevant provisions of this Directive.

3. It is noted further that this proposed Directive makes reference to the conformity assessment requirements set out in Council Directive 92/53/EEC of 18 June 1992 amending Directive 70/156/EEC on the approximation of the laws of the Member States relating to the type approval of motor vehicles and their trailers. It is recognized that under the provisions of this Directive a manufacturer cannot be accredited as a testing laboratory. However, it is permissible for a testing laboratory to use outside equipment, subject to the approval of the Designating Authority.

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

SCOPE AND COVERAGE

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

Products for export to the European Community	Products for export to Australia
Products falling within the scope of Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels.	Products falling within the scope of Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels and which are subject to the Australian legislative and regulatory requirements listed in Section I of this Sectoral Annex.

SECTION I

LEGISLATIVE, REGULATORY AND ADMINISTRATIVE REQUIREMENTS

The legislative, regulatory and administrative requirements of the European Community with which Australian designated Conformity Assessment Bodies shall assess compliance	The legislative, regulatory and administrative requirements of Australia with which European Community designated Conformity Assessment Bodies shall assess compliance
Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels, as amended.	The following legislative, regulatory and administrative requirements cover the conformity assessment procedures for the use of products covered by this Sectoral Annex. New South Wales Victoria • Occupational Health and Safety Act 1985 ([1]) • Occupational Health and Safety (Plant) Regulations 1995 ([1]) • Code of Practice for Plant ([1]) • Equipment (Public Safety) Act 1994 ([1]) • Equipment (Public Safety) (General) Regulations 1995 ([1]) Queensland • Workplace Health & Safety Act 1995 • Workplace Health & Safety Regulation 1995 • Relevant Compliance Standards • Relevant Advisory Standards Western Australia • Occupational Safety and Health Regulations 1996 ([1]) There are no mandatory conformity assessment requirements under this legislation.

	South Australia • Occupational Health, Safety & Welfare Act 1986 • Occupational Health, Safety & Welfare Regulations 1995 Tasmania • Workplace Health & Safety Act 1995 Australian Capital Territory Northern Territory • Work Health Act • Work Health (Occupational Health and Safety) Regulations

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess products against the European Community's legislative, regulatory and administrative requirements	The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrative requirements
The designated Conformity Assessment Bodies are: [Names and details to be inserted] [Note: Further names and details to be added as required]	The designated Conformity Assessment Bodies are: [Names and details to be inserted] [Note: Further names and details to be added as required]

SECTION III

THE AUTHORITIES RESPONSIBLE FOR DESIGNATING
THE CONFORMITY ASSESSMENT BODIES LISTED IN SECTION II

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Commission
Under the authority of the Government of Australia: (a) For Certification Bodies: • The Joint Accreditation System of Australia and New Zealand (JAS-ANZ). (b) For Testing Laboratories and Inspection Bodies: • The National Association of Testing Authorities, Australia (NATA)	• Belgium Ministère de l'Economie Ministerie van Economie • Denmark Direktoratet for Arbejdstilsynet • Germany Bundesministerium für Arbeit und Sozialordnung • Greece Υπουργείο Ανάπτυξης Ministry of Development • Spain Ministerio de Industria y Energía • France Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction de l'action régionale de la petite et moyenne industrie Sous direction de la sécurité industrielle Ministère de l'économie, des finances et de l'industrie Secrétariat d'Etat à l'industrie Direction générale des stratégies industrielles Sous direction de la qualité et de la normalisation • Ireland Department of Enterprise and Employment

	• Italy Ministero dell' Industria, del Commercio e dell' Artigianato • Luxembourg Ministère des Transports • Netherlands Staat der Nederlanden • Austria Bundesministerium für wirtschaftliche Angelegenheiten • Portugal Under the authority of the Government of Portugal: Instituto Português da Qualidade • Finland Kauppa- ja teollisuusministeriö/ Handels- och industriministeriet • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • UK Department of Trade and Industry

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess products against the European Community's requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess products against Australia's requirements
The Conformity Assessment Bodies listed in Section II 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 harmonization directives, and are designated on the basis of the procedures defined in the Annex to the Agreement. This may be demonstrated through: (i) Product Certification Bodies operating according to the requirements of EN 45011 or ISO Guides 28 and 40, and either: (a) accredited by JAS-ANZ, or (b) able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement.	1. Where the laws and regulations listed in Section I make compliance with AS 3920.1 and Australian standards for pressure equipment mandatory, the Conformity Assessment Bodies listed in Section II are designated by the Designating Authorities specified in Section III in accordance with the following criteria: (i) Design Verification Bodies complying with AS 3920.1 and (a) operating within a quality system meeting the requirements of ISO 9001 and certified by a Quality Systems Certification Body operating according to the requirements of ISO Guide 62 or EN 45012, and either: • accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification • accredited by an accreditation body with whom JAS-ANZ has a mutual recognition agreement, or

(ii) Quality System Certification Bodies operating according to the requirements of EN 45012 or ISO Guide 62, and either: (a) accredited by JAS-ANZ, or (b) able to demonstrate competence by other means in accordance with Sections A and B of the Annex to the Agreement. (iii) Inspection Bodies operating according to the requirements of EN 45004 or ISO Guide 39, and either: (a) accredited by NATA, or (b) able to demonstrate competence by other means in accordance with Sections A or B of the Annex to the Agreement.	• able to demonstrate competence under an equivalent accreditation scheme, and (b) operating in conformity with EN 45004 or ISO Guide 39 and accredited by an accreditation body meeting the requirements of ISO Guide 58 or EN 45002/3 (ii) Inspection Bodies complying with AS 3920.1 and operating according to the requirements of ISO Guide 39 or EN 45004, and either: (a) accredited by an accreditation body which is a signatory to a European Multilateral Agreement, or (b) able to demonstrate competence under an equivalent accreditation scheme (iii) Testing Laboratories operating according to the requirements of ISO Guide 25 or EN 45001, and either: (a) accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing, or (b) able to demonstrate competence under an equivalent accreditation scheme.

	(iv) Quality Systems Certification Bodies complying with AS 3920.1 and operating according to the requirements of ISO Guide 62 or EN 45012, and either: (a) accredited by an accreditation body which is a signatory to the European cooperation for Accreditation (EA) Multilateral Agreement on Certification, or (b) accredited by an accreditation body with whom JAS-ANZ has a mutual recognition agreement, or (c) able to demonstrate competence under an equivalent accreditation scheme. 2. Where AS 3920.1 is not mandatory, i.e. it may be referred to in a Code of Practice/Advisory Standard as one means of compliance with the legislation listed in Section I, a designer or a manufacturer may choose to follow item 1 above. Alternatively, the designer or manufacturer may choose alternative conformity assessment procedures which will ensure that the pressure equipment complies with the performance duties of the relevant laws and regulations of the particular jurisdiction.

	It is noted that pressure equipment that complies with and has been subject to the conformity assessment process contained in Council Directive 87/404/EEC of 25 June 1987 on the harmonization of the laws of the Member States relating to simple pressure vessels may satisfy the obligations on designers and manufacturers as provided for in the legislation listed in Section I. 3. For Victoria there are no mandatory conformity assessment requirements under the legislation listed in Section I, other than that the design must be verified by someone who did not participate in the design of the plant subject to design verification.

SECTION V

ADDITIONAL PROVISIONS

In respect of pressure equipment which is subject to the provisions of Council Directive 73/23/EEC of 19 February 1973 on the harmonization of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility, the relevant provisions of the Sectoral Annexes on, respectively, Low Voltage Equipment and Electromagnetic Compatibility shall apply.

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

SCOPE AND COVERAGE

In accordance with the terms of this Annex, Australia shall recognize and accept results of testing, conformity of production and approval procedures according to Regulations adopted in the context of the UN/ECE 1958 Agreement (UN/ECE Regulations), deemed to be equivalent to EC Directives, carried out in the European Community, where these Regulations are substantially equivalent to Australian regulatory provisions.

In accordance with the terms of this Annex, the European Community shall accept results of testing and conformity of production procedures carried out in Australia in accordance with the Council Directives for which there is a UN/ECE Regulation, which is fully or partially/conditionally applied by Australia and is recognized as substantially equivalent in Annex IV, Part 2 of Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type approval of motor vehicles and their trailers, as last amended.

In accordance with the terms of this Annex, Parties shall recognize and accept results of testing and conformity of production procedures carried out by the other Party to that Party's requirements in areas where substantial equivalence between regulatory provisions of both Parties is established.

The provision of this Sectoral Annex shall apply to automotive products and vehicle components as specified in the following Regulations from the Economic Commission for Europe: 1, 3-8, 11, 12, 13 for N and O-category vehicles, 14, 16-21, 23-25, 30, 37, 38, 43, 46, 48, 49, 51 and 83, in their latest applicable version as well as to EC Directives/ADRs on speed-limiting devices, defrosting and demisting systems and windscreen wiper/washer systems, as last amended.

The scope and coverage of this Sectoral Annex will be adapted according to changes in the position on substantial equivalence between UN/ECE Regulations and the regulatory provisions in force in Australia and the European Community.

SECTION I

REGULATORY REQUIREMENTS

The regulatory requirements of the European Community with which Australian designated Conformity Assessment Bodies shall assess compliance	The regulatory requirements of Australia with which European Community designated Conformity Assessment Bodies shall assess compliance
The relevant testing and conformity of production procedures for the purpose of this Annex are those defined in the following Council Directives in amended form, as appropriate:	The relevant testing, conformity of production and approval procedures for the purpose of this Annex are those defined in the following law, Regulations and Australian Design Rules in their latest applicable version:
• Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type approval of motor vehicles and their trailers	• Motor Vehicles Standards Act 1989, and • Motor Vehicles Standards Regulations
• Council Directive 70/157/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the permissible sound level and the exhaust system of motor vehicles	• Australian Design Rule 28/01 External noise of motor vehicles of 30 March 1994
• Council Directive 70/220/EEC of 20 March 1970 on the approximation of the laws of the Member States relating to measures to be taken against air pollution by gases from positive-ignition engines of motor vehicles	• Australian Design Rule 37/00 Emission control for light vehicles of 30 March 1994 • Australian Design Rule 37/01 Emission control for light vehicles of 12 December 1995 • Australian Design Rule 70/00 Exhaust emission control for diesel engined vehicles of 29 September 1993

• Council Directive 70/387/EEC of 27 July 1970 on the approximation of the laws of the Member States relating to the doors of motor vehicles and their trailers	• Australian Design Rule 2/00 Side door latches and hinges of 20 May 1992
• Council Directive 71/127/EEC of 1 March 1971 on the approximation of the laws of the Member States relating to the rear-view mirrors of motor vehicles	• Australian Design Rule 14/02 Rear vision mirrors of 20 May 1992
• Council Directive 71/320/EEC of 26 July 1971 on the approximation of the laws of the Member States relating to the braking devices of certain categories of motor vehicles and their trailers	• Australian Design Rule 35/00 Commercial vehicle braking systems of 30 June 1993 • Australian Design Rule 38/00 Trailer brake systems of 17 July 1991 • Australian Design Rule 38/01 Trailer brake systems of 22 September 1994
• Council Directive 72/306/EEC of 2 August 1972 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of pollutants from diesel engines for use in vehicles	• Australian Design Rule 30/00 Diesel engine exhaust smoke emission of 20 May 1992
• Council Directive 74/60/EEC of 17 December 1973 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (interior parts of the passenger compartment other than the interior rear-view mirrors, layout of controls, the roof or sliding roof, the backrest and rear part of the seats)	• Australian Design Rule 11/00 Internal sunvisors of 20 May 1992

• Council Directive 74/61/EEC of 17 December 1973 on the approximation of the laws of the Member States relating to devices to prevent the unauthorized use of motor vehicles	• Australian Design Rule 25/02 Anti-theft lock of 29 March 1995
• Council Directive 74/297/EEC of 4 June 1974 on the approximation of the laws of the Member States relating to interior fittings of motor vehicles (the behaviour of the steering mechanism in the event of an impact)	• Australian Design Rule 10/01 Steering column of 16 December 1992
• Council Directive 74/408/EEC of 22 July 1974 on the approximation of the laws of the Member States relating to the interior fittings of motor vehicles (strength of seats and their anchorages) • Council Directive 76/115/EEC of 18 December 1975 on the approximation of the laws of the Member States relating to anchorages for motor-vehicle safety belts	• Australian Design Rule 3/01 Seat anchorages of 20 May 1992 • Australian Design Rule 3/02 Seats and seat anchorages of 29 September 1993 • Australian Design Rule 5/02 Anchorages for seat belts and child restraints of 30 June 1993 • Australian Design Rule 5/03 Anchorages for seat belts of 21 December 1994
• Council Directive 76/756/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to the installation of lighting and light-signalling devices on motor vehicles and their trailers • Council Directive 76/757/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to reflex reflectors for motor vehicles and their trailers	• Australian Design Rule 13/00 Installation of lighting and light-signalling devices on other than L-group vehicles of 12 December 1995 • Australian Design Rule 47/00 Reflex reflectors of 20 May 1992

• Council Directive 76/758/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to the end-outline marker lamps, front position (side) lamps, rear position (side) lamps, stop lamps, daytime running lamps and side marker lamps for motor vehicles and their trailers	• Australian Design Rule 49/00 Front & rear position (side) lamps, stop lamps & end-outline marker lamps of 20 May 1992
• Council Directive 76/759/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to direction indicator lamps for motor vehicles and their trailers	• Australian Design Rule 6/00 Direction indicator lamps of 20 May 1992
• Council Directive 76/760/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to the rear registration plate lamps for motor vehicles and their trailers	• Australian Design Rule 48/00 Rear registration plate illuminating devices of 20 May 1992
• Council Directive 76/761/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to motor-vehicle headlamps which function as main-beam and/or dipped-beam headlamps and to incandescent electric filament lamps for such headlamps	• Australian Design Rule 46/00 Headlamps of 20 May 1992 • Australian Design Rule 51/00 Filament globes of 12 December 1995
• Council Directive 76/762/EEC of 27 July 1976 on the approximation of the laws of the Member States relating to front fog lamps for motor vehicles and filament lamps for such lamps	• Australian Design Rule 50/00 Front fog lamps of 20 May 1992
• Council Directive 77/538/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to rear fog lamps for motor vehicles and their trailers	• Australian Design Rule 52/00 Rear fog lamps of 20 May 1992

• Council Directive 77/539/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to reversing lamps for motor vehicles and their trailers	• Australian Design Rule 1/00 Reversing lamps of 20 May 1992
• Council Directive 77/541/EEC of 28 June 1977 on the approximation of the laws of the Member States relating to safety belts and restraint systems for motor vehicles	• Australian Design Rule 4/01 Seat belts of 30 March 1994 • Australian Design Rule 4/02 Seat belts of 21 December 1994
• Council Directive 78/317/EEC of 21 December 1977 on the approximation of the laws of the Member States relating to the defrosting and demisting systems of glazed surfaces of motor vehicles	• Australian Design Rule 15/01 Demisting of windscreen of 20 May 1992
• Council Directive 78/318/EEC of 21 December 1977 on the approximation of the laws of the Member States relating to the wiper and washer systems of motor vehicles	• Australian Design Rule 16/01 Windscreen wipers and washers of 20 May 1992
• Council Directive 78/932/EEC of 16 October 1978 on the approximation of the laws of the Member States relating to head restraints of seats of motor vehicles	• Australian Design Rule 22/00 Head restraints of 12 December 1995
• Council Directive 88/77/EEC of 3 December 1987 on the approximation of the laws of the Member States relating to the measures to be taken against the emission of gaseous pollutants from diesel engines for use in vehicles	• Australian Design Rule 70/00 Exhaust emission control for diesel engined vehicles of 29 September 1993

• Council Directive 92/22/EEC of 31 March 1992 on safety glazing and glazing materials on motor vehicles and their trailers	• Australian Design Rule 8/00 Safety glazing material of 20 May 1992 • Australian Design Rule 8/01 Safety glazing material of 12 December 1995
• Council Directive 92/23/EEC of 31 March 1992 relating to tyres for motor vehicles and their trailers and to their fitting	• Australian Design Rule 23/01 Passenger car tyres of 12 December 1995
• Council Directive 92/24/EEC of 31 March 1992 relating to speed-limitation devices or similar speed-limitation on-board systems of certain categories of motor vehicles	• Australian Design Rule 65/00 Maximum road speed limiting for heavy goods vehicles and vehicle omnibuses of 18 July 1990

SECTION II

DESIGNATED CONFORMITY ASSESSMENT BODIES

The Conformity Assessment Bodies designated by Australia to assess products against the European Community's regulatory requirements	The Conformity Assessment Bodies designated by the European Community to assess products against Australia's legislative, regulatory and administrative requirements
Federal Office of Road Safety PO Box 594 Canberra ACT 2601 Australia	The designated Conformity Assessment Bodies are: [Name and details to be inserted] [Further names to be added as required]

SECTION III

AUTHORITIES RESPONSIBLE FOR
DESIGNATING CONFORMITY OF ASSESSMENT BODIES

For the Conformity Assessment Bodies designated by Australia	For the Conformity Assessment Bodies designated by the European Community
The Administrator of Vehicle Standards delegated by the Australian Minister for Transport under the provisions of the Motor Vehicle Standards Act 1989	• Belgium Ministère des Communications et de l'Infrastructure Ministerie van Verkeer en Infrastructuur • Denmark Færdselsstyrelsen • Germany Bundesministerium für Verkehr • Greece Υπουργείο Μεταφορών Ministry of Transport

	• Spain Ministerio de Industria y Energía • France Ministère de l'équipement, des transports et du logement Direction de la sécurité et de la circulation routière Sous direction de la réglementation technique des véhicules • Ireland Department of Enterprise and Employment • Italy Ministero dei Trasporti • Luxembourg Ministère des Transports • Netherlands Dienst Wegverkeer (RDW Centrum voor Voertuigtechniek en Informatie) • Austria Bundesministerium für Wissenschaft und Verkehr • Portugal Direcção-General de Viação • Finland Liikenneministeriö/Trafikministeriet • Sweden Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) • UK Vehicle Certification Agency

SECTION IV

PROCEDURES FOR DESIGNATING CONFORMITY ASSESSMENT BODIES

The procedures to be followed by Australia in designating Conformity Assessment Bodies to assess products against the European Community's regulatory requirements	The procedures to be followed by the European Community in designating Conformity Assessment Bodies to assess products against Australia's regulatory requirements
The principles set out in the Annex to the Agreement For Testing Laboratories: • The Administrator of Vehicle Standards may authorize officers from the Federal Office of Road Safety to supervise testing of vehicle components and vehicle systems specified in Section I of this Sectoral Annex. • The Administrator of Vehicle Standards, following advice from the National Association of Testing Authorities, Australia (NATA) may designate laboratories to conduct tests on the vehicle and vehicle components specified in Section I of this Sectoral Annex.	The principles set out in the Annex to the Agreement For Testing Laboratories: The following procedures are deemed to be consistent with the procedures set out in the Annex to the Agreement. • Technical Services appointed under the provisions of Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type approval of motor vehicles and their trailers, as amended by Council Directive 92/53/EEC, to conduct tests specified in the Australian Design Rules for Motor Vehicles and Trailers. • Laboratories accredited under national accreditation systems or recognized under the provisions of the European cooperation for Accreditation (EA) Multilateral Agreement on Calibration and Testing. • Bodies able to demonstrate competence and designated by the authorities listed in Section III.

Conformity of Production: The following procedures are deemed to be consistent with the procedures set out in the Annex to the Agreement. • The Administrator of Vehicle Standards may authorize suitably qualified officers of the Federal Office of Road Safety to conduct conformity assessments of vehicle component manufacturers in accordance with the requirements of Annex X of Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type approval of motor vehicles and their trailers. • Further, the Administrator of Vehicle Standards may designate Conformity Assessment Bodies that have been accredited by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ) to conduct assessments in accordance with the requirements of Annex X of Council Directive 70/156/EEC of 6 February 1970 on the approximation of the laws of the Member States relating to the type approval of motor vehicles and their trailers	Conformity of Production: The following procedures are deemed to be consistent with the procedures set out in the Annex to the Agreement. • A certification body complying with harmonized standard EN 45012, and either qualified as such by the approval authority of a Member State itself, or accredited as such by a national accreditation organization of a Member State and recognized by that Member State's approval authority to conduct assessments to the ISO 9001 quality management standard as defined in Administrator's Circular 0-13-2.

SECTION V

ADDITIONAL PROVISIONS

1. Lighting

The Parties note that for certain Australian Design Rules concerned with vehicle lighting and included in Section I of this Sectoral Annex, i.e. Australian Design Rules 49/00, 6/00, 48/00, 50/00, 52/00 and 1/00, it is a requirement to test with filament globes complying with Australian Design Rule 51/00 which is considered equivalent to UN/ECE Regulation 37.

2. Standstill

In areas not covered by the Sectoral Annex, the Parties agree not to introduce changes to their certification arrangements other than those introduced by the establishment of this Agreement, which would make these arrangements less favourable in their effect than those currently prevailing.

3. Review

This Sectoral Annex shall be reviewed two years after its entry into force in the light of developments in relation to international standardization in the area of vehicles and parts, in particular as far as Australia and the European Community are concerned.

4. Extension

The Parties shall advise one another of adoption of requirements that align with Regulations from the Economic Commission for Europe. Where notification has been received that both Australia and the European Community have adopted a UN/ECE Regulation, the Joint Committee shall adopt appropriate amendments for inclusion in the listing given in Section I of this Sectoral Annex.

FINAL ACT

The plenipotentiaries of:

the EUROPEAN COMMUNITY, hereinafter referred to as "the Community",

of the one part, and

the plenipotentiary of AUSTRALIA,

of the other part,

meeting for the signature of the Agreement on Mutual Recognition in relation to Conformity Assessment between the European Community and Australia, hereinafter referred to as the "Agreement", have adopted the following texts:

the Agreement including its Annex and the following Sectoral Annexes relating to:

1. Medicinal Products GMP Inspection and Batch Certification

2. Medical Devices

3. Telecommunications Terminal Equipment

4. Low Voltage Equipment

5. Electromagnetic Compatibility

6. Machinery

7. Pressure Equipment

8. Automotive Products

The plenipotentiaries of the Community and the plenipotentiary of Australia have adopted the texts of the Joint Declarations listed below and annexed to this Final Act:

– Joint Declaration relating to future work on implementing arrangements for this Agreement

– Joint Declaration on mutual recognition in the voluntary sphere

– Joint Declaration relating to further developing harmonization of technical regulations and conformity assessment procedures

– Joint Declaration relating to the review of Article 4 of the Agreement.

ANNEX

JOINT DECLARATION
RELATING TO FUTURE WORK ON IMPLEMENTING ARRANGEMENTS
FOR THIS AGREEMENT

1. Pressure Equipment

The Parties will extend the scope of the Sectoral Annex on Pressure Equipment and start negotiations to that effect once the new Directive on this subject, at present being examined in the Council of the European Union and the European Parliament on the basis of a European Commission proposal, has entered into force.

2. Aircraft certification and continued airworthiness

The Parties confirm their intention to continue negotiations in order to complete the Sectoral Annex in respect of aircraft certification and continued airworthiness, with the view to its establishment as an implementing arrangement for this Agreement no later than two years following its entry into force.

3. Inclusion of other Sectoral Annexes

To build on this Agreement, Australia and the European Community will commence negotiations on the further extension of the sectoral coverage of the Agreement two years from the date that the Agreement enters into force.

JOINT DECLARATION
ON MUTUAL RECOGNITION IN THE VOLUNTARY SPHERE

The Parties will encourage their non-governmental bodies to cooperate with the view to establishing mutual recognition arrangements in the voluntary sphere.

JOINT DECLARATION

RELATING TO FURTHER DEVELOPING HARMONIZATION

OF TECHNICAL REGULATIONS AND CONFORMITY ASSESSMENT PROCEDURES

The Parties will give consideration to increasing the degree of harmonization or equivalence of their respective technical regulations and conformity assessment procedures, where appropriate and where consistent with good regulatory practice. The Parties acknowledge that one objective could be the establishment where feasible of a single submission and evaluation procedure, applicable in both Parties, for the products covered by the Agreement.

JOINT DECLARATION

RELATING TO THE REVIEW OF ARTICLE 4 OF THE AGREEMENT

The Parties will consider a broadening of the provisions of Article 4 to include other countries once the Parties have concluded equivalent Agreements on Mutual Recognition in relation to conformity assessment in the same sectors with those other countries.
