AGREEMENT

on mutual recognition between the European Community and Japan

THE EUROPEAN COMMUNITY and JAPAN (hereinafter referred to as 'the parties');

CONSIDERING the traditional friendly relations that exist between the European Community and Japan;

RECOGNISING the significance of mutual recognition of the results of conformity assessment procedures in facilitating market access and promoting trade between the parties;

CONSIDERING the common interest in enhancing product quality, with a view to ensuring the health and safety of the public and protecting the environment;

RECOGNISING the OECD principles of good laboratory practice (GLP);

RECALLING that long and fruitful cooperative activities of the European Community and Japan have made contributions to international development and harmonisation of good manufacturing practice (GMP) requirements;

BEING AWARE of the positive contribution that mutual recognition agreements can make to encouraging international harmonisation of standards, and

BEARING IN MIND the obligations of the parties as Members of the World Trade Organisation, and being conscious, *inter alia*, of their obligations under the Agreement on Technical Barriers to Trade (hereinafter referred to as the 'WTO Agreement on Technical Barriers to Trade') included in Annex 1A, and the Agreement on Trade-related Aspects of Intellectual Property Rights (hereinafter referred to as the 'WTO Agreement on Trade-related Aspects of Intellectual Property Rights') included in Annex 1C of the Marrakesh Agreement Establishing the World Trade Organisation (hereinafter referred to as the 'WTO Agreement'),

HAVE AGREED AS FOLLOWS:

Article 1

1. For the purposes of this Agreement:

(a) the term 'conformity assessment procedure' means any procedure to determine, directly or indirectly, whether products or processes fulfil relevant technical requirements set out in the applicable laws, regulations and administrative provisions of a party;

(b) the term 'conformity assessment body' means a body which conducts conformity assessment procedure, and the term 'registered conformity assessment body' means the conformity assessment body registered pursuant to Article 9 of this Agreement;

(c) the term 'designation' means the designation of conformity assessment bodies by a designating authority of a party pursuant to the applicable laws, regulations and administrative provisions of that party;

(d) the term 'designating authority' means an authority of a party with the power to designate, monitor, withdraw the designation of, suspend the designation of, and withdraw the suspension of the designation of the conformity assessment bodies in its territory that conduct conformity assessment procedures based upon requirements set out in the applicable laws, regulations and administrative provisions of the other party;

(e) the term 'criteria for designation' means the criteria which conformity assessment bodies of a party are required to fulfil in order to be designated by the designating authority of that party, and other relevant conditions which designated conformity assessment bodies are required to continuously fulfil after the designation, as set out in the applicable laws, regulations and administrative provisions of the other party specified in the relevant Sectoral Annex;

(f) the term 'confirmation' means the confirmation of the compliance of manufacturing facilities or test facilities (hereinafter referred to as 'facilities') with the criteria for confirmation by a competent authority of a party pursuant to the applicable laws, regulations and administrative provisions of that party;

(g) the term 'competent authority' means an authority of a party with the power to conduct inspection or study audits on facilities in its territory to confirm their compliance with the criteria for confirmation set out in the applicable laws, regulations and administrative provisions of that party;

(h) the term 'criteria for confirmation' means the criteria which a facility of a party is required to continuously fulfil in order to be confirmed by the cauthority of the party, as set out in the applicable laws, regulations and administrative provisions of that party specified in the relevant Sectoral Annex, and

(i) the term 'verification' means an action to verify in the territories of the parties, by such means as audits or inspections, compliance with the criteria for designation or the criteria for confirmation by a conformity assessment body or a facility respectively.

2. Any term used in this Agreement, unless otherwise defined herein, has the meaning assigned to it in the ISO/IEC Guide 2: 1996 Edition, 'Standardisation and related activities — General vocabulary'.

Article 2

1. Each party shall accept, in accordance with the provisions of this Agreement, the results of conformity assessment procedures required by the applicable laws, regulations and administrative provisions of that party specified in the relevant Sectoral Annex, including certificates and marks of conformity, that are conducted by the registered conformity assessment bodies of the other party.

2. Each party shall accept, in accordance with the provisions of this Agreement:

(a) the confirmation of facilities conducted by the competent authorities of the other party based on the results of verification and in accordance with the criteria for confirmation stipulated in the laws, regulations and administrative provisions of that other party as specified in the relevant Sectoral Annex, and

(b) the data generated by confirmed facilities of the other party.

Article 3

1. This Agreement applies to designation of conformity assessment bodies, conformity assessment procedures for products or processes, and to confirmation of facilities and data generated by them, covered by its Sectoral Annexes. Sectoral Annexes may consist of Part A and Part B.

2. Part A of Sectoral Annexes shall include, *inter alia,* provisions on scope and coverage.

3. Part B of Sectoral Annexes shall set out the following matters:

(a) the applicable laws, regulations and administrative provisions of each party concerning the scope and coverage;

(b) the applicable laws, regulations and administrative provisions of each party stipulating the requirements covered by this Agreement, all the conformity assessment procedures covered by this Agreement to satisfy such requirements and the criteria for designation of conformity assessment bodies, or the applicable laws, regulations and administrative provisions of each party stipulating the criteria for confirmation of the facilities covered by this Agreement, and

(c) the list of designating authorities or competent authorities.

Article 4

1. Each party shall ensure that designating authorities have the necessary power to designate, monitor (including verification), withdraw the designation of, suspend the designation of and withdraw the suspension of the designation of the conformity assessment bodies that conduct conformity assessment procedures based on the requirements set out in the applicable laws, regulations and administrative provisions of the other party specified in the relevant Sectoral Annex.

2. Each party shall ensure that competent authorities have the necessary power to conduct, in accordance with its applicable laws, regulations and administrative provisions, verification of facilities to confirm their compliance with the criteria for confirmation set out in the applicable laws, regulations and administrative provisions of that party specified in the relevant Sectoral Annex.

Article 5

1. Each party shall ensure, through appropriate means such as audits, inspections or monitoring, that the registered conformity assessment bodies fulfil the criteria for designation set out in the applicable laws, regulations and administrative provisions of the other party specified in the relevant Sectoral Annex. When applying the criteria for designation of the conformity assessment bodies, designating authorities of a party should take into account the bodies' understanding of and experience relevant to the requirements set out in the applicable laws, regulations and administrative provisions of the other party.

2. Each party shall, in accordance with its applicable laws, regulations and administrative provisions and through appropriate means such as study audits, inspections or monitoring, ensure that the confirmed facilities fulfil the criteria for confirmation set out in the applicable laws, regulations and administrative provisions of that party specified in the relevant Sectoral Annex.

3. Each party may request the other party, by indicating in writing a reasoned doubt on whether a registered conformity assessment body or a confirmed facility complies with the

criteria for designation or the criteria for confirmation set out in the applicable laws, regulations and administrative provisions specified in the relevant Sectoral Annex, respectively, to conduct verification of the conformity assessment body or the facility in accordance with the laws, regulations and administrative provisions of that other party.

4. Each party may, on request, participate as an observer in the verification of conformity assessment bodies conducted by the designating authorities or the verification of facilities conducted by the competent authorities of the other party, with the prior consent of such conformity assessment bodies or such facilities respectively, in order to maintain a continuing understanding of that other party's procedures for verification.

5. The parties shall, in accordance with the procedures to be determined by the Joint Committee to be established pursuant to Article 8, exchange information on methods, including accreditation systems, used to designate the conformity assessment bodies and to ensure that the registered conformity assessment bodies fulfil the criteria for designation and on methods to ensure that the confirmed facilities fulfil the criteria for confirmation.

6. Each party should encourage its registered conformity assessment bodies to cooperate with the conformity assessment bodies of the other party.

Article 6

1. In case of suspension of the designation of a registered conformity assessment body, the party whose designating authority has suspended the designation shall immediately notify the other party and the Joint Committee to that effect. The registration of that conformity assessment body shall be suspended from the time of receipt of the notification by the co-chairman of that other party on the Joint Committee. The other party shall accept the results of the conformity assessment procedures conducted by that conformity assessment body prior to the suspension of the designation.

2. In case of lifting of the suspension of the designation of a registered conformity assessment body, the party whose designating authority has lifted the suspension of the designation shall immediately notify the other party and the Joint Committee to that effect. The suspension of the registration of that conformity assessment body shall be lifted from the time of receipt of the notification by the co-chairman of that other party on the Joint Committee. The other party shall accept the results of the conformity assessment procedures conducted by that conformity assessment body from the time of lifting of the suspension of the registration.

Article 7

1. Each party may contest the compliance with the criteria for designation or the criteria for confirmation set out in the applicable laws, regulations and administrative provisions specified in the relevant Sectoral Annex by a registered conformity assessment body or a confirmed facility of the other party, respectively. Such contestation shall be notified to the Joint Committee and to that other party in writing with an objective explanation of the reason for the contestation. The Joint Committee shall discuss such contestation within 20 days of the date on which such notification is made.

2. Where the Joint Committee decides to conduct a joint verification, it will be conducted in a timely manner by the parties with the participation of the designating authority that designated the contested conformity assessment body and with the prior consent of the conformity assessment body. The result of such joint verification shall be discussed in the Joint Committee with a view to resolving the issue as soon as possible.

3. The registration of the contested conformity assessment body shall be suspended 15 days after the date on which the notification is made or on the date on which the Joint Committee decides to suspend the registration, whichever is the sooner. The registration of the contested conformity assessment body shall remain suspended until the Joint Committee decides to lift the suspension of the registration of the conformity assessment body. In the event of such suspension, the contesting party shall accept the results of conformity assessment procedures conducted by that conformity assessment body prior to the date of suspension.

4. The Joint Committee will decide on the actions to be taken by a party or parties with a view to resolving issues concerning the contestation of facilities as soon as possible.

5. The contesting party shall not be obliged to accept the confirmation of and the data generated by the contested facility from the date on which the co-chairman of the other party on the Joint Committee receives the notification referred to in paragraph 1 until the date on which the Joint Committee decides otherwise.

Article 8

1. A Joint Committee made up of representatives of both parties shall be established on the date of the entry into force of this Agreement, as a body responsible for the effective functioning of this Agreement.

2. The Joint Committee shall take decisions and adopt recommendations by consensus. It shall meet at the request of either party under the co-chairmanship of both parties. The Joint Committee may establish subcommittees and delegate specific tasks to such subcommittees. It shall adopt its rules of procedure.

3. The Joint Committee may consider any matter related to the operation of this Agreement. In particular, it shall be responsible for and/or decide on:

(a) registration of a conformity assessment body, suspension of registration of a conformity assessment body, lifting of suspension of registration of a conformity assessment body, and termination of registration of a conformity assessment body;

(b) establishment and, unless otherwise decided, publication on a sector-by-sector basis of lists of the registered conformity assessment bodies and the confirmed facilities;

(c) establishment of appropriate modalities of information exchange referred to in this Agreement, and

(d) appointment of experts from each party for the joint verification referred to in Article 7(2) and (c) and Article 9(1)(c).

4. If any problem arises to the interpretation or application of this Agreement, the parties shall seek an amicable solution through the Joint Committee.

5. The Joint Committee is responsible for coordinating and facilitating the negotiation of additional Sectoral Annexes.

6. Each party shall provide the other party and the Joint Committee, at least annually, with a list of the confirmed facilities.

7. Any decision made by the Joint Committee will be notified promptly in writing to each party.

8. The parties shall, through the Joint Committee:

(a) specify and communicate to each other the applicable articles or annexes contained in the laws, regulations and administrative provisions set out in the Sectoral Annexes;

(b) exchange information concerning the implementation of the applicable laws, regulations and administrative provisions specified in the Sectoral Annexes;

(c) notify each other of any scheduled changes in the laws, regulations and administrative provisions related to this Agreement prior to their entry into force, and

(d) notify each other of any scheduled changes concerning their designating authorities, competent authorities, the registered conformity assessment bodies and the confirmed facilities.

Article 9

1. The following procedure shall apply to the registration of a conformity assessment body:

(a) each party shall make a proposal that a conformity assessment body of that party designated by its designating authority be registered under this Agreement, by presenting its proposal in writing, supported by necessary documents, to the other party and the Joint Committee;

(b) the other party shall consider whether the proposed conformity assessment body complies with the criteria for designation set out in the applicable laws, regulations and administrative provisions of that other party specified in the relevant Sectoral Annex and indicate its position regarding the registration of that conformity assessment body within 90 days of receipt of the proposal referred to in subparagraph (a). In such consideration, such other party should assume that the proposed conformity assessment body complies with the aforementioned criteria. The Joint Committee shall take a decision whether to register the proposed conformity assessment body within 90 days of the receipt of the proposal;

(c) in the event that the Joint Committee cannot decide to register the proposed conformity assessment body, the Joint Committee may decide to conduct a joint verification or to request the proposing party to conduct a verification of the proposed body with the prior consent of such body. After the completion of such verification, the Joint Committee may reconsider the proposal.

2. The proposing party shall provide the following information in its proposal for registration of a conformity assessment body and keep such information up to date:

(a) the name and address of the conformity assessment body;

(b) the products or processes the conformity assessment body is authorised to assess;

(c) the conformity assessment procedures the conformity assessment body is authorised to conduct, and

(d) the designation procedure and necessary information used to determine the compliance of the conformity assessment body with the criteria for designation.

3. Each party shall ensure that its designating authority withdraws the designation of a registered conformity assessment body when the designating authority considers that the conformity assessment body no longer complies with the criteria for designation set out in the applicable laws, regulations and administrative provisions of the other party specified in the relevant Sectoral Annex.

4. Each party shall propose the termination of the registration of its conformity assessment body when that party considers that the conformity assessment body no longer complies with the criteria for designation set out in the

applicable laws, regulations and administrative provisions of the other party specified in the relevant Sectoral Annex, or the designating authority of that party withdraws the designation of a conformity assessment body. Proposals for terminating the registration of that conformity assessment body shall be made to the Joint Committee and the other party. The registration of that conformity assessment body shall be terminated on receipt of the proposal by the co-chairman of that other party on the Joint Committee, unless otherwise determined by the Joint Committee.

5. In the case of the registration of a new conformity assessment body, the other party shall accept the results of conformity assessment procedures conducted by that conformity assessment body from the date of the registration. In the event that the registration of a conformity assessment body is terminated, the other party shall accept the results of the conformity assessment procedures conducted by that conformity assessment body prior to the termination, without prejudice to 6(1) and Article 7(3).

Article 10

1. Nothing in this Agreement shall be construed to limit the authority of a party to take measures it considers appropriate, for protecting health, safety or the environment or prevention of deceptive practices.

2. (a) The competent authority of a party may visit manufacturing facilities of the other party on the condition that such other party and the manufacturing facilities concerned consent to such visit and, if such other party so requests, officials of the competent authority of such other party join the visit, for the purpose of deciding whether to continue to accept the confirmation of the manufacturing facilities concerned and the data generated by them pursuant to Article 2(2), where an emergency as defined in subparagraph (b) of this paragraph takes place. Such visit shall be carried out in a manner not inconsistent with the laws and regulations of that other party and in accordance with the modalities to be decided pursuant to subparagraph (b) of this paragraph. The party shall use the information obtained by its competent authority in connection with such visit only for the purpose above.

(b) The definition of the emergency and the modalities of such visit referred to in subparagraph (a) of this paragraph will be decided by the Joint Committee as part of the preparatory work to be done in accordance with the provisions of the relevant Sectoral Annex.

Article 11

1. Without prejudice to Article 2(2), nothing in this Agreement shall entail mutual acceptance of the standards or technical regulations of the parties.

2. Nothing in this Agreement shall be construed to entail an obligation on a party to accept the result of the conformity assessment procedures of any non-member country.

3. Nothing in this Agreement shall be construed so as to affect the rights and obligations that either party has as a member of the WTO Agreement, including the WTO Agreement on Technical Barriers to Trade and the WTO Agreement on Trade-related Aspects of Intellectual Property Rights.

Article 12

This Agreement shall apply to the territories in which the Treaty establishing the European Community is applied under the conditions laid down in that Treaty and to the territory of Japan.

Article 13

Neither party shall disclose any information obtained under this Agreement as confidential, unless otherwise required under the laws or regulations of each party.

Article 14

1. This Agreement shall enter into force on the first day of the second month following the date on which the parties exchange diplomatic notes informing each other that their respective internal procedures necessary to give effect to this Agreement have been completed.

2. Either party may terminate this Agreement by giving the other party six months written notice.

Article 15

1. The Sectoral Annexes to this Agreement are an integral part of this Agreement.

2. In case of conflict between the provisions of Part A of a Sectoral Annex and Articles 1 to 15 of this Agreement, the provisions of Part A of the Sectoral Annex shall prevail.

3. (a) The provisions concerning the scope and coverage of paragraph 1 of Part A of each Sectoral Annex shall not be changed unless the parties amend this Agreement in accordance with the first sentence of subparagraph (b) of this paragraph.

(b) This Agreement may be amended by agreement between the parties. However, if the amendments relate only to changes of laws, regulations and administrative provisions, designating authorities or competent authorities specified in Part B of the Sectoral Annexes,

the amendments may be made by exchange of diplomatic notes between the European Community and the Government of Japan, in conformity with their applicable domestic procedures.

4. If a party introduces new or additional conformity assessment procedures within the same product coverage to satisfy the requirements set out in the applicable laws, regulations and administrative provisions specified in the relevant Sectoral Annex, Part B of the Sectoral Annex shall be amended to set out the applicable laws, regulations and administrative provisions stipulating such new or additional conformity assessment procedures, in accordance with the procedures set out in the second sentence of subparagraph (b) of paragraph 3 of this Article.

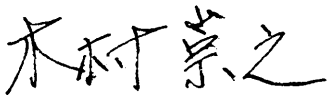
This Agreement and its Annexes are drawn up in two originals in the Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish, Swedish and Japanese languages. In case of divergence the English and Japanese versions shall prevail over the other language versions.

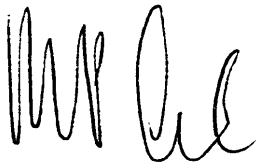
IN WITNESS WHEREOF, the undersigned, being duly authorised, have signed this Agreement.

Done at Brussels, on the fourth day of April in the year two thousand and one.

For the European Community

For Japan





SECTORAL ANNEX ON TELECOMMUNICATIONS TERMINAL EQUIPMENT AND RADIO EQUIPMENT

PART A

Scope and coverage

1. This Sectoral Annex applies to conformity assessment procedures for all telecommunications terminal equipment and radio equipment, which in the European Community and Japan respectively are subject to conformity assessment procedures conducted by the conformity assessment body, as set out in the laws, regulations and administrative provisions of each party specified in Section I of Part B of this Sectoral Annex.

2. It is understood that the term 'amendment' referred to in Part B of this Sectoral Annex includes the following cases:

(a) a party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether or not those names are changed;

(b) a party repeals its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and/or administrative provisions substituting for the previous laws, regulations and/or administrative provisions, whether or not the previous names are changed, and

(c) a party incorporates the whole or a relevant part of its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and/or administrative provisions.

PART B

Section I: The applicable laws, regulations and administrative provisions stipulating telecommunications terminal equipment and radio equipment

European Community	Japan
1. Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity and amendments thereto	1. Telecommunications Business Law (Law No 86, 1984) and amendments thereto 2. Ordinance concerning technical conditions compliance approval and certification of the type for ferminal equipment (Ordinance of the Ministry of Posts and Telecommunications No 14, 1999) and amendments thereto 3. Radio Law (Law No 131, 1950) and amendments thereto 4. Ordinance concerning technical regulations conformity certification of specified radio equipment (Ordinance of the Ministry of Posts and Telecommunications No 37, 1981) and amendments thereto

Section II: The applicable laws, regulations and administrative provisions stipulating the requirements and the conformity assessment procedures

European Community	Japan
1. Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity and amendments thereto	1. Telecommunications Business Law (Law No 86, 1984) and amendments thereto
2. For electrical safety: Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and amendments thereto, in so far as this Directive applies to equipment covered by this Sectoral Annex	2. Ordinance concerning terminal facilities etc. (Ordinance of the Ministry of Posts and Telecommunications No 31, 1985) and amendments thereto
3. For electromagnetic compatibility: Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and amendments thereto, in so far as this Directive applies to equipment covered by this Sectoral Annex	3. Ordinance concerning technical conditions compliance approval and certification of the type for terminal equipment (Ordinance of the Ministry of Posts and Telecommunications No 14, 1999) and amendments thereto
	4. Ordinance for attested examiners etc. on telecommunications business law (Ordinance of the Ministry of Posts and Telecommunications No 15, 1999) and amendments thereto
	5. Radio Law (Law No 131, 1950) and amendments thereto
	6. Ordinance regulating radio equipment (Radio Regulatory Commission Regulations No 18, 1950) and amendments thereto
	7. Ordinance concerning technical regulations conformity certification of specified radio equipment (Ordinance of the Ministry of Posts and Telecommunications No 37, 1981) and amendments thereto
	8. Ordinance concerning attested private inspectors etc. (Ordinance of the Ministry of Posts and Telecommunications No 76, 1997) and amendments thereto

Section III: Designating authorities

European Community	Japan
Designating authorities of the European Community are the following authorities of the Member States of the European Community or authorities succeeding them: *Belgium* Institut belge des services postaux et des télécommunications/Belgisch Instituut voor postdiensten en telecommunicatie For EMC aspects Ministère des affaires économiques/Ministerie van Economische Zaken *Denmark* Telestyrelsen *Germany* Bundesministerium für Wirtschaft und Technologie *Greece* Υπουργείο Μεταφορών καί Επικοινωνιών *Spain* Ministerio de Ciencia y Tecnología, Subdirección General de Infrastructuras y Normativa Técnica *France* Ministère de l'économie, des finances et de l'industrie, Direction générale de l'industrie, des technologies de l'information et des postes (DiGITIP) *Ireland* Department of Public Enterprise *Italy* Ministero dell'Industria, del Commercio e dell'Artigianato *Luxembourg* Entreprise des Postes et Télécommunications *Netherlands* Ministerie van Verkeer en Waterstaat *Austria* Bundesministerium für Verkehr, Innovation und Technologie *Portugal* Instituto das Comunicações de Portugal *Finland* Liikenne- ja viestintäministeriö/Kommunikationsministeriet *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) *United Kingdom* Department of Trade and Industry	Designating authorities of Japan are the following authorities or authorities succeeding them: For Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity and amendments thereto: Ministry of Public Management, Home Affairs, Posts and Telecommunications For Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of Member States relating to electrical equipment designed for use within certain voltage limits and amendments thereto: Ministry of Public Management, Home Affairs, Posts and Telecommunications Ministry of Economy, Trade and Industry

Section IV: The applicable laws, regulations and administrative provisions stipulating the criteria for designation

The criteria to be applied by Japan in designating conformity assessment bodies to assess products against the European Community's requirements	The criteria to be applied by the European Community in designating conformity assessment bodies to assess products against Japan's requirements
1. Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity and amendments thereto	1. Telecommunications Business Law (Law No 86, 1984) and amendments thereto
2. Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and amendments thereto	2. Ordinance concerning technical conditions compliance approval and certification of the type for terminal equipment (Ordinance of the Ministry of Posts and Telecommunications No 14, 1999) and amendments thereto
3. Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and amendments thereto	3. Ordinance for attested examiners etc. on telecommunications business law (Ordinance of the Ministry of Posts and Telecommunications No 15, 1999) and amendments thereto
4. 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 EC conformity marking, which are intended to be used in the technical harmonisation directives and amendments thereto, to be taken into account	4. Radio Law (Law No 131, 1950) and amendments thereto
	5. Ordinance concerning technical regulations conformity certification of specified radio equipment (Ordinance of the Ministry of Posts and Telecommunications No 37, 1981) and amendments thereto
	6. Ordinance concerning attested private inspectors etc. (Ordinance of the Ministry of Posts and Telecommunications No 76, 1997) and amendments thereto

SECTORAL ANNEX ON ELECTRICAL PRODUCTS

PART A

Scope and coverage

1. This Sectoral Annex applies to conformity assessment procedures for all electrical products, which in the European Community and Japan respectively are subject to conformity assessment procedures conducted by the conformity assessment body, as set out in the laws, regulations and administrative provisions of each party specified in Section I of Part B of this Sectoral Annex.

2. It is understood that the term 'amendment' referred to in Part B of this Sectoral Annex includes the following cases:

(a) a party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether or not those names are changed;

(b) a party repeals its applicable laws, regulations and /or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and/or administrative provisions substituting for the previous laws, regulations and/or administrative provisions, whether or not the previous names are changed; and

(c) a party incorporates the whole or a relevant part of its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and/or administrative provisions.

PART B

Section I: The applicable laws, regulations and administrative provisions stipulating electrical products

European Community	Japan
1. Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and amendments thereto, excluding equipment falling within the scope of the Sectoral Annex on telecommunications terminal equipment and radio equipment 2. With regard to the electromagnetic compatibility aspects of the above products, Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and amendments thereto	1. Electrical appliance and material safety law (Law No 234, 1961) and amendments thereto 2. Cabinet Order of the electrical appliance and material safety law (Cabinet Order No 324, 1962) and amendments thereto

Section II: The applicable laws, regulations and administrative provisions stipulating the requirements and the conformity assessment procedures

European Community	Japan
1. Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and amendments thereto 2. Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and amendments thereto, insofar as this Directive applies to equipment covered by this Sectoral Annex	1. Electrical appliance and material safety law (Law No 234, 1961) and amendments thereto 2. Ordinance of the electrical appliance and material safety law (Ordinance of the Ministry of International Trade and Industry No 84, 1962) and amendments thereto 3. Ordinance concerning technical requirements for electrical appliances and materials (Ordinance of the Ministry of International Trade and Industry No 85, 1962) and amendments thereto 4. Working Regulations for the Ordinance concerning technical requirements for electrical appliances and materials (50 Shikobu No 192, 1975) and amendments thereto

Section III: Designating authorities

European Community	Japan
Designating authorities of the European Community are the following authorities of the Member States of the European Community or authorities succeeding them: *Belgium* Ministère des affaires économiques/Ministerie van Economische Zaken *Denmark* By- og Boligministeriet For EMC aspects: Telestyrelsen *Germany* Bundesministerium für Arbeit und Sozialordnung For EMC aspects: Bundesministerium für Wirtschaft und Technologie *Greece* Υπουργείο Ανάπτυξης *Spain* Ministerio de Ciencia y Tecnología, Subdirección General de Calidad y Seguridad Industrial *France* Ministère de l'économie, des finances et de l'industrie, Direction générale de l'industrie, des technologies de l'information et des postes (DiGITIP) *Ireland* Department of Enterprise, Trade and Employment *Italy* Ministero dell'Industria, del Commercio e dell'Artigianato *Luxembourg* Ministère des Transports *Netherlands* Ministerie van Verkeer en Waterstaat *Austria* Bundesministerium für Wirtschaft und Arbeit *Portugal* Under the authority of the Government of Portugal Instituto Português da Qualidade (IPQ) *Finland* Kauppa- ja teollisuusministeriö/Handels- och industriministeriet *Sweden* Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC) *United Kingdom* Department of Trade and Industry	Ministry of Economy, Trade and Industry or an authority succeeding this ministry

Section IV: The applicable laws, regulations and administrative provisions stipulating the criteria for designation

The criteria to be applied by Japan in designating conformity assessment bodies to assess products against the European Community's requirements	The criteria to be applied by the European Community in designating conformity assessment bodies to assess products against Japan's requirements
1. Council Directive 73/23/EEC of 19 February 1973 on the harmonisation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits and amendments thereto	1. Electrical appliance and material safety law (Law No 234, 1961) and amendments thereto
2. Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility and amendments thereto	2. Cabinet Order of the electrical appliance and material safety law (Cabinet Order No 324, 1962) and amendments thereto
3. 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 EC conformity marking, which are intended to be used in the technical harmonisation directives and amendments thereto, to be taken into account	3. Ordinance of the electrical appliance and material safety law (Ordinance of the Ministry of International Trade and Industry No 84, 1962) and amendments thereto

SECTORAL ANNEX ON GOOD LABORATORY PRACTICE (GLP) FOR CHEMICALS

PART A

1. This Sectoral Annex applies to:

   (a) the confirmation of the compliance of test facilities with the principles of GLP for the testing of chemicals, being either substances or preparations, as set out in the laws, regulations and administrative provisions of each party specified in Section I of Part B of this Sectoral Annex; and,

   (b) the acceptance of the data generated by confirmed test facilities.

2. (a) For the purpose of this Sectoral Annex:

      (i) 'criteria for confirmation' are the principles of GLP as stipulated in the laws, regulations and administrative provisions of each party specified in Section III of Part B of this Sectoral Annex and that are consistent with Annex II of the OECD Council Decision of 12 May 1981 (C(81)30 (final)) as amended by the OECD Council Decision of 26 November 1997 (C(97) 186 (final)), and

      (ii) 'verification' means the monitoring of the compliance of a test facility with the principles of GLP by procedures such as study audits and inspections that are set out in the laws, regulations and administrative provisions of each party specified in Section III of Part B of this Sectoral Annex and that are consistent with the OECD Council Decision — Recommendation of 2 October 1989 (C(89) 87(final)), and in particular its Annexes I and II, as amended by the OECD Council Decision of 9 March 1995 (C(95)8(final)).

   (b) For the purpose of this Sectoral Annex, any term, unless otherwise defined in this Agreement, has the meaning assigned to it in the 'OECD Principles of good laboratory practice' as contained in Annex II of the OECD Council Decision of 12 May 1981 (C(81)30(final)), the 'Guides for compliance monitoring procedures for good laboratory practice' as contained in Annex I of the OECD Council Decision — Recommendation of 2 October 1989 (C(89)87(final)), the GLP Consensus Document 'The Application of the GLP Principles to Field Studies' (OECD Series on Principles of good laboratory practice and compliance monitoring, Number 6), and all amendments made thereto.

   (c) It is understood that the term 'amendment' referred to in Part B of this Sectoral Annex includes the following cases:

      (i) a party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether or not those names are changed;

      (ii) a party repeals its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and/or administrative provisions substituting for the previous laws, regulations and/or administrative provisions, whether or not the previous names are changed, and

      (iii) a party incorporates the whole or a relevant part of its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and/or administrative provisions.

   (d) In making amendments to the laws, regulations and administrative provisions specified in Section III of this Sectoral Annex, the parties should take account of the need to maintain consistency with the relevant decisions and recommendations of the OECD.

3. With respect to Article 2(2) of this Agreement, each party shall, as a result of the acceptance of the confirmation of test facilities by the competent authorities of the other party, accept the data for a test item generated by the confirmed test facilities as equivalent to the data generated by its own test facilities which are confirmed to be compliant with the principles of GLP, taking into account the equivalence of GLP compliance monitoring programme of both parties, which are consistent with the OECD Council Decision-Recommendation of 2 October 1989 (C(89)87 (final)) as amended by the OECD Council Decision of 9 March 1995 (C (95) 8 (final)), provided that:

   (a) a certificate or an alternative document on the GLP compliance status of the test facility issued by the competent authority of that other party, in accordance with the applicable laws, regulations and administrative provisions of that other party specified in Section III of Part B of this Sectoral Annex, is attached to the data, and

   (b) the testing for which the data is generated is covered by the principles of GLP in both parties pursuant to the applicable laws, regulations and administrative provisions of each party;

4. (a) The list of the confirmed facilities referred to in Article 8(3) and (6) of this Agreement shall be provided in an appropriate agreed format and include the following information:

      (i) the name and address of the test facility;

(ii) the dates of verification or confirmation;

(iii) the GLP compliance status, and

(iv) the areas of expertise as listed in point 4 of the Appendix to Annex III of the OECD Council Decision-Recommendation of 2 October 1989 (C (89) 87 (final)).

(b) each party shall, to the extent possible, provide the other party with additional information on the confirmed facilities upon a reasoned request by that other party;

(c) each party shall transmit to the other party, without delay, information on any withdrawal of the certificate of a confirmed test facility if the facility has been found to be non-compliant with the principles of GLP.

5. (a) Each party may request the other party, by indicating in writing a reasoned doubt on whether a study was conducted in accordance with the principles of GLP, to conduct further inspections or study audits on a confirmed test facility, in accordance with the applicable laws, regulations and administrative provisions of that other party;

(b) the requested party shall inform the requesting party of the results of the inspections or study audits, or provide an explanation why such an inspection or study audit has not been carried out;

(c) the requesting party shall not be obliged to accept the data generated by the test facility concerned from the date on which the request is made, until the results of the further inspection or study audit conducted by the competent authority of the requested party have re-confirmed the compliance of the test facility with the principles of GLP;

(d) If, in exceptional cases, doubts persist, and the requesting party can justify a specific concern, that party may contest the compliance of the test facility concerned in accordance with the provisions of Article 7 of this Agreement.

PART B

Section I: The applicable laws, regulations and administrative provisions stipulating the coverage of chemicals subject to testing in accordance with the principles of GLP

European Community	Japan
1. Medicinal Products: (a) Council Directive 87/19/EEC of 22 December 1986 amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products and amendments thereto (b) Commission Directive 91/507/EEC of 19 July 1991 modifying the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products and amendments thereto 2. Veterinary Medicinal Products: (a) Council Directive 87/20/EEC of 22 December 1986 amending Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products and amendments thereto (b) Commission Directive 92/18/EEC of 20 March 1992 modifying the Annex to Council Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products and amendments thereto	1. Pharmaceuticals: (a) Pharmaceutical affairs law (Law No 145, 1960) and amendments thereto (b) Ordinance of the pharmaceutical affairs law (Ordinance of the Ministry of Health and Welfare No 1, 1961) and amendments thereto 2. Veterinary Drugs: (a) Pharmaceutical affairs law (Law No 145, 1960) and amendments thereto (b) Ordinance on the control of veterinary drugs etc. (Ordinance of the Ministry of Agriculture and Forestry No 3, 1961) and amendments thereto 3. Agricultural Chemicals: Agricultural chemicals regulation law (Law No 82, 1948) and amendments thereto 4. Feed Additives: (a) Law concerning safety assurance and quality improvement of feed (Law No 35, 1953) and amendments thereto (b) Re: the Establishment of the standards for evaluation of feed additives (4 Chiku A No 201 (1992)) and amendments thereto

European Community	Japan
3. Plant Protection Products: Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market as last amended by Commission Directive 95/35/EC of 14 July 1995 and amendments thereto 4. Biocides: Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market and amendments thereto 5. Feed Additives: Council Directive 87/153/EEC of 16 February 1987 fixing guidelines for the assessment of additives in animal nutrition as amended by Commission Directive 94/40/EC of 22 July 1994 and amendments thereto 6. New and Existing Chemicals: (a) Council Directive 92/32/EEC of 30 April 1992 amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances and amendments thereto (b) Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations and amendments thereto (c) Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances and amendments thereto 7. Food Additives: (a) Council Directive 89/397/EEC of 14 June 1989 on the official control of foodstuffs and amendments thereto (b) Council Directive 93/99/EEC of 29 October 1993 on the subject of additional measures concerning the official control of foodstuffs and amendments thereto 8. Cosmetics: Council Directive 93/35/EEC of 14 June 1993 amending for the sixth time Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products and amendments thereto	5. New Substances and Designated Substances: (a) Law concerning the examination and regulation of manufacture etc. of chemical substances (Law No 117, 1973) and amendments thereto (b) Ordinance prescribing test items etc. relating to new chemical substances and toxicity research of designated chemical substances (Ordinance of the Prime Minister's Office, the Ministry of Health and Welfare and the Ministry of International Trade and Industry No 1, 1974) and amendments thereto 6. Substances controlled for the prevention of health hazard of workers: (a) Industrial safety and health law (Law No 57, 1972) and amendments thereto (b) Ordinance on industrial safety and health (Ordinance of the Ministry of Labour No 32, 1972) and amendments thereto

Section II: Competent authorities

European Community	Japan
Competent Authorities of the European Community are the following authorities of the Member States of the European Community or authorities succeeding them: *Belgium* For all: Institut scientifique de la santé publique/Wetenschappelijk Instituut Volksgezondheid *Denmark* For industrial chemicals: Erhvervsfremmestyrelsen For medicinal products: Lægemiddelstyrelsen *Germany* For all: Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit *Greece* For all: Γενικό Χημείο του Κράτους *Spain* For medicinal products: Agencia Española del Medicamento, Subdirección General de Seguridad de Medicamentos For pesticides: Ministerio de Agricultura, Pesca y Alimentación, Dirección General de Agricultura For industrial chemicals: Ministerio de Ciencia y Tecnología, Subdirección General de Calidad y Seguridad Industrial For additives: Ministerio de Sanidad y Consumo, Subdirección General de Seguridad Alimentaria For biocides: Ministerio de Sanidad y Consumo, Subdirección General de Sanidad Ambiental y Salud Laboral *France* For industrial chemicals, pesticides and other than medicinal products and cosmetics: Groupe interministériel des produits chimiques For medicinal products (except veterinary medicinal products) and cosmetics: Agence française de sécurité sanitaire des produits de santé (AFSSAPS)	Competent authorities of Japan are the following authorities or authorities succeeding them: For pharmaceuticals: Ministry of Health, Labour and Welfare For veterinary drugs: Ministry of Agriculture, Forestry and Fisheries For agricultural chemicals: Ministry of Agriculture, Forestry and Fisheries For feed additives: Ministry of Agriculture, Forestry and Fisheries For new substances and designated substances: Ministry of Health, Labour and Welfare Ministry of Economy, Trade and Industry For substances controlled for the prevention of health hazards to workers: Ministry of Health, Labour and Welfare

European Community	Japan
For veterinary medicinal products:	
Agence française de sécurité sanitaire des aliments	
Agence nationale du médicament vétérinaire	
Ireland	
For all:	
National Accreditation Board	
Italy	
For all:	
Ministero della Sanità	
Netherlands	
For all:	
Ministerie van Volksgezondheid, Welzijn en Sport,	
Inspectie voor de Gezondheidszorg (GLP-afdeling)	
Austria	
For all:	
Bundesministerium für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft	
Portugal	
For industrial chemicals and pesticides:	
Under the authority of the Government of Portugal:	
Instituto Português da Qualidade (IPQ)	
Ministério da Economia	
For medicinal products and veterinary medicinal products:	
Instituto Nacional da Farmácia e do Medicamento (Infarmed)	
Finland	
For all:	
Sosiaali- ja terveydenhuollon tuotevalvontakeskus/	
Social- och hälsovårdens produkttillsynscentral	
Sweden	
For medicinal products, veterinary medicinal products, hygiene and cosmetics products:	
Läkemedelsverket	
For all other products:	
Styrelsen för ackreditering och teknisk kontroll (Swedac)	
United Kingdom	
For all:	
Department of Health,	
Good Laboratory Practice Monitoring Authority	

Section III: The applicable laws, regulations and administrative provisions stipulating the principles of GLP, verification and confirmation

European Community	Japan
1. Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances as last amended by Commission Directive 1999/11/EC of 8 March 1999 and amendments thereto 2. Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of good laboratory practice (GLP), as last amended by Commission Directive 1999/12/EC of 8 March 1999 and amendments thereto	1. Pharmaceuticals: (a) Pharmaceutical Affairs Law (Law No 145, 1960) and amendments thereto (b) Ordinance prescribing standards for the conduct of non-clinical laboratory studies on safety of drugs (Ordinance of the Ministry of Health and Welfare No 21, 1997) and amendments thereto (c) Re: treatment of materials concerning non-clinical laboratory studies on safety of drugs which should be attached to the application for the product (import) approval etc. (Yakushin No 253 (1997) — Yakuan No 29 (1997)) and amendments thereto (d) Re: the establishment of the guidelines for the conduct of GLP on-site inspection (Yakushin No 254 (1997) — Yakuan No 30 (1997)) and amendments thereto 2. Veterinary drugs: (a) Pharmaceutical Affairs Law (Law No 145, 1960) and amendments thereto (b) Ordinance prescribing standards for the conduct of non-clinical laboratory studies on safety of veterinary drugs (Ordinance of the Ministry of Agriculture, Forestry and Fisheries No 74, 1997) and amendments thereto (c) Re: management of the Pharmaceutical Affairs Law (12 Chiku A No 729 (2000)) and amendments thereto 3. Agricultural chemicals: (a) Agricultural Chemicals Regulation Law (Law No 82, 1948) and amendments thereto (b) Re: the proper implementation of toxicological studies on agricultural chemicals (11 Nosan No 6283 (1999)) and amendments thereto 4. Feed additives: (a) Law concerning safety assurance and quality improvement of feed (Law No 35, 1953) and amendments thereto (b) Re: standards for the conduct of animal studies on feed additives (63 Chiku A No 3039 (1988)) and amendments thereto (c) Re: the establishment of the guidelines for the inspection based on the standards for the conduct of animal studies on feed additives (1 Chiku A No 3441 (1990)) and amendments thereto

European Community	Japan
	5. New substances and designated substances: (a) Law concerning the examination and regulation of manufacture etc. of chemical substances (Law No 117, 1973) and amendments thereto (b) Re: standard concerning testing facility provided for in Article 4 of the Ordinance prescribing test items etc. relating to new chemical substances and toxicity research of designated chemical substances (Kanpogyo No 39 (1984) — Yakuhatsu No 229 (1984) — 59 Kikyoku No 85 (1984)) and amendments thereto (c) Re: test results used as criteria for determination at the examination etc. of new chemical substances (Eisei No 39 (1988) — 63 Kikyoku No 822 (1988)) and amendments thereto 6. Substances controlled for the prevention of health hazards to workers: (a) Industrial Safety and Health Law (Law No 57, 1972) and amendments thereto (b) The standard to be satisfied by the test facility etc. under the provisions of Article 34-3(2) of the Ordinance on industrial safety and health (Notice of the Ministry of Labour No 76, 1988) and amendments thereto (c) Re: implementation of the Ordinance to amend a part of the Ordinance on industrial safety and health, the Ordinance to amend a part of the Ordinance on safety of boiler and high pressure vessels and the Ordinance to amend a part of the Ordinance on preventing organic solvents poisoning, etc. (Kihatsu No 602 (1988)) and amendments thereto (d) Re: the establishment of the guideline of certification of compliance of test facilities etc. with GLP under the Industrial Safety and Health Law (Kihatsu No 123 (1989)) and amendments thereto

SECTORAL ANNEX ON GOOD MANUFACTURING PRACTICE (GMP) FOR MEDICINAL PRODUCTS

PART A

1. This Sectoral Annex applies:

   (a) to the confirmation of the compliance with GMP requirements of manufacturing facilities for medicinal products to which the GMP requirements of both parties are applied in accordance with the laws, regulations and administrative provisions of each party specified in Section I of Part B of this Sectoral Annex, and

   (b) to the acceptance of the data generated by confirmed manufacturing facilities (the certificate issued by confirmed manufacturing facilities in accordance with the provisions of Part A of this Sectoral Annex).

2. For the purpose of this Sectoral Annex:

   (a) the term 'medicinal products' means drugs which are industrially manufactured for human use as defined in the laws, regulations and administrative provisions of Japan specified in Section I of Part B of this Sectoral Annex, and medicinal products and intermediate products which are industrially manufactured for human use as defined in the laws, regulations and administrative provisions of the European Community in Section I of Part B of this Sectoral Annex.

   The definition of medicinal products above may include medicinal products intended for clinical trials, active ingredients, chemical and biological pharmaceuticals, immunologicals, radiopharmaceuticals, stable medicinal products derived from human blood or human plasma and, where appropriate, vitamins, minerals and herbal medicines.

   (b) The term 'criteria for confirmation' means the GMP requirements.

   (c) The term 'good manufacturing practice (GMP)' means that part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use and as required by the applicable marketing authorisation or product specifications.

   (d) The term 'inspection' means an on-site evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with GMP requirements including the requirements of the applicable marketing authorisation or product specifications. Such inspection is conducted in accordance with the laws, regulations and administrative provisions specified in Section I of Part B of this Sectoral Annex carried out by a competent authority listed in Section II of Part B of this Sectoral Annex, and may include pre-marketing and post-marketing inspection.

   (e) It is understood that the term 'amendment' referred to in Part B of this Sectoral Annex includes the following cases:

      (i) a party entirely or partially changes its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex, whether or not those names are changed;

      (ii) a party repeals its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex and adopts new laws, regulations and/or administrative provisions substituting for the previous laws, regulations and/or administrative provisions, whether or not the previous names are changed, and

      (iii) a party incorporates the whole or a relevant part of its applicable laws, regulations and/or administrative provisions listed in Part B of this Sectoral Annex into other laws, regulations and/or administrative provisions.

3. This Agreement does not cover mutual recognition of batch release (Kentei) referred to in Article 43 of the Pharmaceutical Affairs Law (Law No 145, 1960) of Japan and batch release referred to in Article 4 of Council Directive 89/342/EEC of 3 May 1989 and in Article 4 of Council Directive 89/381/EEC of 14 June 1989.

4. With respect to Article 2(2) of this Agreement, each party shall, as a result of the acceptance of confirmation of manufacturing facilities carried out by the competent authorities of the other party, accept, regarding the medicinal products for which its marketing authorisation has been issued or for which product specifications are applicable, the certificate issued by the confirmed manufacturing facilities of the conformity of each batch to the marketing authorisation or product specifications and exempt the importers from the testing of each batch, in accordance with the laws, regulations and administrative provisions of each party specified in the Section I of Part B of this Sectoral Annex, taking into account the equivalence of GMP requirements of both parties, provided that:

   (a) such certificate is issued by the confirmed manufacturing facilities on the results of a full qualitative analysis, a quantitative analysis of all the active constituents and all the other tests or checks;

   (b) the certificate contains a statement that the product has been manufactured in conformity with GMP requirements, and

   (c) both parties apply the equivalent GMP requirements for the products to which the certificate is issued.

5. In the certificate issued by the confirmed manufacturing facilities and related to each batch to be exported, as referred to in paragraph 4, it will be certified, through the testing which is required for the manufacturing of medicinal products in accordance with the laws, regulations and administrative provisions of each party specified in Section I of Part B of this Sectoral Annex, that each batch of medicinal products is manufactured as required by the applicable marketing authorisation or product specifications of the importing party.

6. A subcommittee of the Joint Committee will be established in particular to monitor the progress of the preparatory work set out in paragraph 9 of this Sectoral Annex and the operation of this Sectoral Annex. It will report to the Joint Committee.

7. (a) The parties will exchange information on, in particular:

   (i) GMP for specific products or classes of products;

   (ii) new technical guidance or inspection procedures;

   (iii) quality defects, batch recalls, counterfeiting and other problems concerning quality;

   (iv) any suspension or withdrawal of a manufacturing authorisation.

   (b) The parties will agree detailed alert procedures through the subcommittee of the Joint Committee to fulfil specific objectives of this Sectoral Annex.

   (c) Equivalence of GMP for specific products or classes of products will be coordinated according to a procedure established by the subcommittee of the Joint Committee.

   (d) Notwithstanding Article 8(6) of this Agreement, each party shall provide the other party and the Joint Committee with a list of the confirmed manufacturing facilities at the frequency to be decided by the Joint Committee.

   (e) Each party will, on reasoned request by the other party, provide a copy of the most recent inspection report on a confirmed facility within 30 days of the date of the request. If the requested party conducts an additional inspection, that party will provide a copy of the report of such additional inspection to the requesting party within 60 days of the date of the request. If after the exchange of inspection reports there remains serious cause for concern on whether a manufacturing facility in the other party complies with GMP requirements, each party may request the other party to conduct further inspections of that facility.

   (f) The competent authority of a party will, on request by an exporter, importer or the competent authority of the other party, confirm that a manufacturing facility in its territory:

      (i) is appropriately authorised to manufacture medicinal products in accordance with its laws, regulations and administrative provisions specified in Section I of Part B of this Sectoral Annex;

      (ii) is regularly inspected by the competent authorities;

      (iii) complies with its GMP requirements that are recognised by both parties as equivalent.

8. With regard to Article 5(2), the exporting party shall, in accordance with its applicable laws, regulations and administrative provisions, inspect periodically the manufacturing facilities in order to ensure that the facilities fulfil its GMP requirements set out in the laws, regulations and administrative provisions of that party specified in Section I of Part B of this Sectoral Annex.

9. (a) Articles 2, 4, 5, 7 and Article 10(2)(a) relating to this Sectoral Annex and the provisions of this Sectoral Annex other than paragraph 6 and paragraph 7(b) and this paragraph shall not be applied before the 30th day after the date of exchange of diplomatic notes confirming to each other that the preparatory work is completed. Such exchange of diplomatic notes is expected to take place within 18 months of the entry into force of this Agreement.

   (b) Through the preparatory work, the parties shall reconfirm the equivalence of GMP requirements and their implementation through the Joint Committee. The Joint Committee will decide the detailed procedures for implementing this Sectoral Annex.

PART B

Section I: The applicable laws, regulations and administrative provisions stipulating medicinal products, GMP requirements for medicinal products, verification and confirmation

European Community	Japan
1. Council Directive 65/65/EEC of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and amendments thereto	1. Pharmaceutical Affairs Law (Law No 145, 1960) and amendments thereto
2. 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 and amendments thereto	2. Cabinet Order of the Pharmaceutical Affairs Law (Cabinet order No 11, 1961) and amendments thereto
3. 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 and amendments thereto	3. Medicinal products designated by the Minister for Health, Labour and Welfare under the provisions of subparagraphs 7 and 8 of Article 1-2-2(1) of the Cabinet order of the Pharmaceutical Affairs Law (Notice of the Ministry of Health and Welfare No 17, 1994) and amendments thereto
4. Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products and amendments thereto	4. Ordinance for facilities and equipments for pharmacies etc. (Ordinance of the Ministry of Health and Welfare No 2, 1961) and amendments thereto
5. The latest version of the 'Guide to good manufacturing practice', Volume 4 of the rules governing medicinal products in the European Union and amendments thereto	5. Ordinance for manufacturing control and quality control for drugs and quasi drugs (Ordinance of the Ministry of Health and Welfare No 16, 1999) and amendments thereto
	6. Ordinance for import and marketing control and quality control for imported drugs and quasi drugs (Ordinance of the Ministry of Health and Welfare No 62, 1999) and amendments thereto

Section II: Competent authorities

European Community	Japan
Competent authorities of the European Community are the following authorities of the Member States of the European Community or authorities succeeding them: *Belgium* Inspection générale de la pharmacie/Algemene Farmaceutische Inspectie *Denmark* Lægemiddelstyrelsen *Germany* Bundesministerium für Gesundheit Paul-Ehrlich Institut (biologicals only) *Greece* Υπουργείο Υγείας και Πρόνοιας Εθνικός οργανισμός φαρμάκων (Ε.Ο.Φ.) *Spain* Agencia Española del Medicamento, Subdirección General de Seguridad de Medicamentos *France* Ministère de l'emploi et de la solidarité, Direction générale de la santé Agence française de sécurité sanitaire des produits de santé (AFSSAPS) *Ireland* Irish Medicines Board *Italy* Ministero della sanità, Dipartimento per la valutazione dei medicinali e la farmacovigilanza *Luxembourg* Division de la pharmacie et des médicaments *Netherlands* Ministerie van Volksgezondheid, Welzijn en Sport, Inspectie voor de Gezondheidszorg *Austria* Bundesministerium für soziale Sicherheit und Generationen *Portugal* Instituto Nacional da Farmácia e do Medicamento (Infarmed) *Finland* Lääkelaitos/Läkemedelsverket *Sweden* Läkemedelsverket *United Kingdom* Medicines Control Agency *European Community* European Agency for the Evaluation of Medicinal Products	Ministry of Health, Labour and Welfare or an authority succeeding this ministry