Agreement on Mutual Recognition

Between

the European Community

and the United States of America

Done at London on the eighteenth day of May in the year one thousand nine hundred and ninety-eight.

For the European Community:

Margaret Beckett
Sir Leon Brittan

For the United States of America:

Charlène Barshefsky

AGREEMENT ON MUTUAL RECOGNITION
BETWEEN
THE EUROPEAN COMMUNITY
AND THE UNITED STATES OF AMERICA

The EUROPEAN COMMUNITY, and the GOVERNMENT OF THE UNITED STATES OF AMERICA, hereinafter referred to as "the Parties",

CONSIDERING the traditional links of friendship that exist between the United States of America (U.S.) and the European Community (EC);

DESIRING to facilitate bilateral trade between them;

RECOGNIZING that mutual recognition of conformity assessment activities is an important means of enhancing market access between the Parties;

RECOGNIZING that an agreement providing for mutual recognition of conformity assessment activities is of particular interest to small and medium-sized businesses in the U.S. and the EC;

RECOGNIZING that any such mutual recognition also requires confidence in the continued reliability of the other Party’s conformity assessments;

RECOGNIZING the importance of maintaining each Party’s high levels of health, safety, environmental and consumer protection;

RECOGNIZING that mutual recognition agreements can positively contribute in encouraging greater international harmonization of standards;

NOTING that this Agreement is not intended to displace private sector bilateral and multilateral arrangements among conformity assessment bodies or to affect regulatory regimes allowing for manufacturers' self-assessments and declarations of conformity.

BEARING IN MIND that the Agreement on Technical Barriers to Trade, an agreement annexed to the Agreement establishing the World Trade Organization (WTO), imposes obligations on the Parties as Contracting Parties to the WTO, and encourages such Contracting Parties to enter into negotiations for the conclusion of agreements for the mutual recognition of results of each other's conformity assessment;

RECOGNIZING that any such mutual recognition needs to offer an assurance of conformity with applicable technical regulations or standards equivalent to the assurance offered by the Party's own procedures;

RECOGNIZING the need to conclude an Agreement on Mutual Recognition (MRA) in the field of conformity assessment with sectoral annexes; and

BEARING in mind the respective commitments of the Parties under bilateral, regional and multilateral environment, health, safety and consumer protection agreements.

HAVE AGREED AS FOLLOWS:

ARTICLE 1

DEFINITIONS

1. The following terms and definitions shall apply to this Agreement only:

- Designating Authority means a body with power to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies as specified under this Agreement.

- Designation means the identification by a Designating Authority of a conformity assessment body to perform conformity assessment procedures under this Agreement.

- Regulatory Authority means a government agency or entity that exercises a legal right to control the use or sale of products within a Party's jurisdiction and may take enforcement action to ensure that products marketed within its jurisdiction comply with legal requirements.

2. Other terms concerning conformity assessment used in this Agreement shall have the meaning given elsewhere in this Agreement or in the definitions contained in Guide 2 (1996 edition) of the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC). In the event of an inconsistency between ISO/IEC Guide 2 and definitions in this Agreement, the definitions in this Agreement shall prevail.

ARTICLE 2

PURPOSE OF THE AGREEMENT

This Agreement specifies the conditions by which each Party will accept or recognize results of conformity assessment procedures, produced by the other Party's conformity assessment bodies or authorities, in assessing conformity to the importing Party's requirements, as specified on a sector-specific basis in the Sectoral Annexes, and to provide for other related cooperative activities. The objective of such mutual recognition is to provide effective market access throughout the territories of the Parties with regard to conformity assessment for all products covered under this Agreement. If any obstacles to such access arise, consultations will promptly be held. In the absence of a satisfactory outcome of such consultations, the Party alleging its market access has been denied, may, within 90 days of such consultation, invoke its right to terminate the Agreement in accordance with Article 21.

ARTICLE 3

GENERAL OBLIGATIONS

1. The United States shall, as specified in the Sectoral Annexes, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory, and administrative provisions of the United States, produced by the other Party's conformity assessment bodies and/or authorities.

2. The European Community and its Member States shall, as specified in the Sectoral Annexes, accept or recognize results of specified procedures, used in assessing conformity to specified legislative, regulatory and administrative provisions of the European Community and its Member States, produced by the other Party's conformity assessment bodies and/or authorities.

3. Where sectoral transition arrangements have been specified in Sectoral Annexes, the above obligations will apply following the successful completion of those sectoral transition arrangements, with the understanding that the conformity assessment procedures utilized assure conformity to the satisfaction of the receiving Party, with applicable legislative, regulatory and administrative provisions of that Party, equivalent to the assurance offered by the receiving Party's own procedures.

ARTICLE 4

GENERAL COVERAGE OF THE AGREEMENT

1. This Agreement applies to conformity assessment procedures for products and/or processes and to other related cooperative activities as described in this Agreement.

2. Sectoral Annexes may include:

(a) a description of the relevant legislative, regulatory and administrative provisions pertaining to the conformity assessment procedures and technical regulations;

(b) a statement on the product scope and coverage;

(c) a list of Designating Authorities;

(d) a list of agreed conformity assessment bodies or authorities or a source from which to obtain a list of such bodies or authorities and a statement of the scope of the conformity assessment procedures for which each has been agreed;

(e) the procedures and criteria for designating the conformity assessment bodies;

(f) a description of the mutual recognition obligations;

(g) a sectoral transition arrangement;

(h) the identity of a sectoral contact point in each Party's territory; and

(i) a statement regarding the establishment of a Joint Sectoral Committee.

3. This Agreement shall not be construed to entail mutual acceptance of standards or technical regulations of the Parties and, unless otherwise specified in a Sectoral Annex, shall not entail the mutual recognition of the equivalence of standards or technical regulations.

ARTICLE 5

TRANSITIONAL ARRANGEMENTS

The Parties agree to implement the transitional commitments on confidence building as specified in the Sectoral Annexes.

1. The Parties agree that each sectoral transitional arrangement shall specify a time period for completion.

2. The Parties may amend any transitional arrangement by mutual agreement.

3. Passage from the transitional phase to the operational phase shall proceed as specified in each Sectoral Annex, unless either Party documents that the conditions provided in such Sectoral Annex for a successful transition are not met.

ARTICLE 6

DESIGNATING AUTHORITIES

The Parties shall ensure that the Designating Authorities specified in the Sectoral Annexes have the power and competence in their respective territories to carry out decisions under this Agreement to designate, monitor, suspend, remove suspension of, or withdraw conformity assessment bodies.

ARTICLE 7

DESIGNATION AND LISTING PROCEDURES

The following procedures shall apply with regard to the designation of conformity assessment bodies and the inclusion of such bodies in the list of conformity assessment bodies in a Sectoral Annex:

(a) The Designating Authority identified in a Sectoral Annex shall designate conformity assessment bodies in accordance with the procedures and criteria set forth in that Sectoral Annex;

(b) A Party proposing to add a conformity assessment body to the list of such bodies in a Sectoral Annex shall forward its proposal of one or more designated conformity assessment bodies in writing to the other Party with a view to a decision by the Joint Committee;

(c) Within 60 days following receipt of the proposal, the other Party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the inclusion in the Sectoral Annex of the proposed conformity assessment body or bodies shall take effect; and

(d) In the event that the other Party contests on the basis of documented evidence the technical competence or compliance of a proposed conformity assessment body, or indicates in writing that it requires an additional 30 days to more fully verify such evidence, such conformity assessment body shall not be included on the list of conformity assessment bodies in the applicable Sectoral Annex. In this instance, the Joint Committee may decide that the body concerned be verified. After the completion of such verification, the proposal to list the conformity assessment body in the Sectoral Annex may be resubmitted to the other Party.

ARTICLE 8

SUSPENSION OF LISTED CONFORMITY ASSESSMENT BODIES

The following procedures shall apply with regard to the suspension of a conformity assessment body listed in a Sectoral Annex:

(a) A Party shall notify the other Party of its contestation of the technical competence or compliance of a conformity assessment body listed in a Sectoral Annex and the contesting Party's intent to suspend such conformity assessment body. Such contestation shall be exercised when justified in an objective and reasoned manner in writing to the other Party;

(b) The conformity assessment body shall be given prompt notice by the other Party and an opportunity to present information in order to refute the contestation or to correct the deficiencies which form the basis of the contestation;

(c) Any such contestation shall be discussed between the Parties in the relevant Joint Sectoral Committee. If there is no Joint Sectoral Committee, the contesting Party shall refer the matter directly to the Joint Committee. If agreement to suspend is reached by the Joint Sectoral Committee or, if there is no Joint Sectoral Committee, by the Joint Committee, the conformity assessment body shall be suspended;

(d) Where the Joint Sectoral Committee or Joint Committee decides that verification of technical competence or compliance is required, it shall normally be carried out in a timely manner by the Party in whose territory the body in question is located, but may be carried out jointly by the Parties in justified cases;

(e) If the matter has not been resolved by the Joint Sectoral Committee within 10 days of the notice of contestation, the matter shall be referred to the Joint Committee for a decision. If there is no Joint Sectoral Committee, the matter shall be referred directly to the Joint Committee. If no decision is reached by the Joint Committee within 10 days of the referral to it, the conformity assessment body shall be suspended upon the request of the contesting Party;

(f) Upon the suspension of a conformity assessment body listed in a Sectoral Annex, a Party is no longer obligated to accept or recognize the results of conformity assessment procedures performed by that conformity assessment body subsequent to suspension. A Party shall continue to accept the results of conformity assessment procedures performed by that conformity assessment body prior to suspension, unless a Regulatory Authority of the Party decides otherwise based on health, safety or environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex; and

(g) The suspension shall remain in effect until agreement has been reached by the Parties upon the future status of that body.

ARTICLE 9

WITHDRAWAL OF LISTED CONFORMITY ASSESSMENT BODIES

The following procedures shall apply with regard to the withdrawal from a Sectoral Annex of a conformity assessment body:

(a) A Party proposing to withdraw a conformity assessment body listed in a Sectoral Annex shall forward its proposal in writing to the other Party;

(b) Such conformity assessment body shall be promptly notified by the other Party and shall be provided a period of at least 30 days from receipt to provide information in order to refute or to correct the deficiencies which form the basis of the proposed withdrawal;

(c) Within 60 days following receipt of the proposal, the other Party shall indicate its position regarding either its confirmation or its opposition. Upon confirmation, the withdrawal from the list in the Sectoral Annex of the conformity assessment body shall take effect;

(d) In the event the other Party opposes the proposal to withdraw by supporting the technical competence and compliance of the conformity assessment body, the conformity assessment body shall not at that time be withdrawn from the list of conformity assessment bodies in the applicable Sectoral Annex. In this instance, the Joint Sectoral Committee or the Joint Committee may decide to carry out a joint verification of the body concerned. After the completion of such verification, the proposal for withdrawal of the conformity assessment body may be resubmitted to the other Party; and

(e) Subsequent to the withdrawal of a conformity assessment body listed in a Sectoral Annex, a Party shall continue to accept the results of conformity assessment procedures performed by that conformity assessment body prior to withdrawal, unless a Regulatory Authority of the Party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex.

ARTICLE 10

MONITORING OF CONFORMITY ASSESSMENT BODIES

The following shall apply with regard to the monitoring of conformity assessment bodies listed in a Sectoral Annex:

(a) Designating Authorities shall assure that their conformity assessment bodies listed in a Sectoral Annex are capable and remain capable of properly assessing conformity of products or processes, as applicable, and as covered in the applicable Sectoral Annex. In this regard, Designating Authorities shall maintain, or cause to maintain, ongoing surveillance over their conformity assessment bodies by means of regular audit or assessment;

(b) The Parties undertake to compare methods used to verify that the conformity assessment bodies listed in the Sectoral Annexes comply with the relevant requirements of the Sectoral Annexes. Existing systems for the evaluation of conformity assessment bodies may be used as part of such comparison procedures;

(c) Designating Authorities shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures. With the consent of both Parties, this consultation may include joint participation in audits/inspections related to conformity assessment activities or other assessments of conformity assessment bodies listed in a Sectoral Annex; and

(d) Designating Authorities shall consult, as necessary, with the relevant Regulatory Authorities of the other Party to ensure that all technical requirements are identified and are satisfactorily addressed.

ARTICLE 11

CONFORMITY ASSESSMENT BODIES

Each Party recognizes that the conformity assessment bodies listed in the Sectoral Annexes fulfil the conditions of eligibility to assess conformity in relation to its requirements as specified in the Sectoral Annexes. The Parties shall specify the scope of the conformity assessment procedures for which such bodies are listed.

ARTICLE 12

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. Each Party shall notify the other Party of legislative, regulatory and administrative changes related to the subject matter of this Agreement at least 60 days before their entry into force. Where considerations of safety, health or environmental protection require more urgent action, a Party shall notify the other Party as soon as practicable.

3. Each Party shall promptly notify the other Party of any changes to its Designating Authorities and/or conformity assessment bodies.

4. The Parties shall exchange information concerning the procedures used to ensure that the listed conformity assessment bodies under their responsibility comply with the legislative, regulatory, and administrative provisions outlined in the Sectoral Annexes.

5. Regulatory Authorities identified in the Sectoral Annexes shall consult as necessary with their counterparts, to ensure the maintenance of confidence in conformity assessment procedures and to ensure that all technical requirements are identified and are satisfactorily addressed.

ARTICLE 13

SECTORAL CONTACT POINTS

Each Party shall appoint and confirm in writing contact points to be responsible for activities under each Sectoral Annex.

ARTICLE 14

JOINT COMMITTEE OF THE PARTIES

1. The Parties hereby establish a Joint Committee consisting of representatives of each Party. The Joint Committee shall be responsible for the effective functioning of the Agreement.

2. The Joint Committee may establish Joint Sectoral Committees comprised of appropriate Regulatory Authorities and others deemed necessary.

3. Each Party shall have one vote in the Joint Committee. The Joint Committee shall make its decisions by unanimous consent. The Joint Committee shall determine its own rules and procedures.

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

(a) listing, suspension, withdrawal and verification of conformity assessment bodies in accordance with this Agreement;

(b) amending transitional arrangements in Sectoral Annexes;

(c) resolving any questions relating to the application of this Agreement and its Sectoral Annexes not otherwise resolved in the respective Joint Sectoral Committees;

(d) providing a forum for discussion of issues that may arise concerning the implementation of this Agreement;

(e) considering ways to enhance the operation of this Agreement;

(f) coordinating the negotiation of additional Sectoral Annexes; and

(g) considering whether to amend this Agreement or its Sectoral Annexes in accordance with Article 21.

5. When a Party introduces new or additional conformity assessment procedures affecting a Sectoral Annex, the Parties shall discuss the matter in the Joint Committee with a view to bringing such new or additional procedures within the scope of this Agreement and the relevant Sectoral Annex.

ARTICLE 15

PRESERVATION OF REGULATORY AUTHORITY

1. Nothing in this Agreement shall be construed to limit the authority of a Party to determine, through its legislative, regulatory and administrative measures, the level of protection it considers appropriate for safety; for protection of human, animal, or plant life or health; for the environment; for consumers; and otherwise with regard to risks within the scope of the applicable Sectoral Annex.

2. Nothing in this Agreement shall be construed to limit the authority of a Regulatory Authority to take all appropriate and immediate measures whenever it ascertains that a product may: (a) compromise the health or safety of persons in its territory; (b) not meet the legislative, regulatory, or administrative provisions within the scope of the applicable Sectoral Annex; or (c) otherwise fail to satisfy a requirement within the scope of the applicable Sectoral Annex. Such measures may include withdrawing the products from the market, prohibiting their placement on the market, restricting their free movement, initiating a product recall, and preventing the recurrence of such problems, including through a prohibition on imports. If the Regulatory Authority takes such action, it shall inform its counterpart authority and the other Party within fifteen days of taking such action, providing its reasons.

ARTICLE 16

SUSPENSION OF RECOGNITION OBLIGATIONS

Either Party may suspend its obligations under a particular Sectoral Annex, in whole or in part, if:

(a) a Party suffers a loss of market access for the Party's products within the scope of the Sectoral Annex as a result of the failure of the other Party to fulfil its obligations under the Agreement;

(b) the adoption of new or additional conformity assessment requirements as referenced in Article 14(5) results in a loss of market access for the Party's products within the scope of the Sectoral Annex because conformity assessment bodies designated by the Party in order to meet such requirements have not been recognized by the Party implementing the requirements; or

(c) the other Party fails to maintain legal and regulatory authorities capable of implementing the provisions of this Agreement.

ARTICLE 17

CONFIDENTIALITY

1. Each Party agrees to maintain, to the extent required under its laws, the confidentiality of information exchanged under this Agreement.

2. In particular, neither Party shall disclose to the public, nor permit a conformity assessment body to disclose to the public, information exchanged under this Agreement that constitutes trade secrets, confidential commercial or financial information, or information that relates to an ongoing investigation.

3. A Party or a conformity assessment body may, upon exchanging information with the other Party or with a conformity assessment body of the other Party, designate the portions of the information that it considers to be exempt from disclosure.

4. Each Party shall take all precautions reasonably necessary to protect information exchanged under this Agreement from unauthorized disclosure.

ARTICLE 18

FEES

Each Party shall endeavor to ensure that fees imposed for services under this Agreement shall be commensurate with the services provided. Each Party shall ensure that, for the sectors and conformity assessment procedures covered under this Agreement, it shall charge no fees with respect to conformity assessment services provided by the other Party.

ARTICLE 19

AGREEMENTS WITH OTHER COUNTRIES

Except where there is written agreement between the Parties, obligations contained in mutual recognition agreements concluded by either Party with a party not a signatory to this Agreement (a third party) shall have no force and effect with regard to the other Party in terms of acceptance of the results of conformity assessment procedures in the third party.

ARTICLE 20

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 the United States.

ARTICLE 21

ENTRY INTO FORCE, AMENDMENT AND TERMINATION

1. This Agreement including its Sectoral Annexes on Telecommunication Equipment, Electromagnetic Compatibility, Electrical Safety, Recreational Craft, Pharmaceutical Good Manufacturing Practices (GMPs), and Medical Devices shall enter into force on the first day of the second month following the date on which the Parties have exchanged letters confirming the completion of their respective procedures for the entry into force of this Agreement.

2. This Agreement including any Sectoral Annex may, through the Joint Committee, be amended in writing by the Parties. The Parties may add a Sectoral Annex upon the exchange of letters. Such Annex shall enter into force 30 days following the date on which the Parties have exchanged letters confirming the completion of their respective procedures for the entry into force of the Sectoral Annex.

3. Either Party may terminate this Agreement in its entirety or any individual Sectoral Annex thereof by giving the other Party six months notice in writing. In the case of termination of one or more Sectoral Annexes, the Parties will seek to achieve by consensus to amend this Agreement, with a view to preserving the remaining Sectoral Annexes, in accordance with the procedures in this Article. Failing such consensus, the Agreement shall terminate at the end of six months from the date of notice.

4. Following termination of the Agreement in its entirety or any individual Sectoral Annex thereof, a Party shall continue to accept the results of conformity assessment procedures performed by conformity assessment bodies under this Agreement prior to termination, unless a Regulatory Authority in the Party decides otherwise based on health, safety and environmental considerations or failure to satisfy other requirements within the scope of the applicable Sectoral Annex.

ARTICLE 22

FINAL PROVISIONS

1. The Sectoral Annexes referred to in Article 21(1), as well as any New Sectoral Annexes added pursuant to Article 21(2), shall form an integral part of this Agreement.

2. For a given product or sector, the provisions contained in the relevant Sectoral Annexes shall apply in the first place, and the provisions of this text in addition to those provisions. In the case of any inconsistency between the provisions of a Sectoral Annex and this text, the Sectoral Annex shall prevail, to the extent of that inconsistency.

3. This Agreement shall not affect the rights and obligations of the Parties under any other international agreement.

4. In the case of the Sectoral Annex on Medical Devices, the Parties shall review the status of such Annex at the end of three years from entry into force.

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. In the event of inconsistencies of interpretation, the English text shall be determinative.

SECTORAL ANNEX
FOR
PHARMACEUTICAL GOOD MANUFACTURING PRACTICES
(GMPs)

PREAMBLE

This Annex constitutes a Sectoral Annex to the Agreement on Mutual Recognition between the United States and the European Community.

CHAPTER 1

DEFINITIONS, PURPOSE, SCOPE AND COVERAGE

Article 1

Definitions

1. "Equivalence" of the regulatory systems means that the systems are sufficiently comparable to assure that the process of inspection and the ensuing inspection reports will provide adequate information to determine whether respective statutory and regulatory requirements of the authorities have been fulfilled. "Equivalence" does not require that the respective regulatory systems have identical procedures.

2. "Enforcement" means action taken by an authority to protect the public from products of suspect quality, safety and efficacy or to assure that products are manufactured in compliance with appropriate laws, regulations, standards and commitments made as part of the approval to market a product.

3. "Good Manufacturing Practices" (GMPs): (The U.S. and EC have agreed to revisit these concepts)

   GMPs mean the requirements found in the respective legislations, regulations, and administrative provisions for methods to be used in, and the facilities or controls to be used for the manufacturing, processing, packing, and/or holding of a drug to assure that such drug meets the requirements as to safety, and has the identity and strength, and meets the quality and purity characteristics that it purports or is represented to possess.

   GMPs are that part of quality assurance which ensures that products are consistently produced and controlled to quality standards. For the purpose of this Annex, GMPs include therefore the system whereby the manufacturer receives the specifications of the product and/or process from the Marketing Authorization/Product Authorization or License holder or applicant and ensures the product is made in compliance with its specifications (Qualified Person certification in the EC).

4. "Inspection" means an on-site evaluation of a manufacturing facility to determine whether such manufacturing facility is operating in compliance with Good Manufacturing Practices and/or commitments made as part of the approval to market a product.

5. "Inspection Report" means the written observations and Good Manufacturing Practices compliance assessment completed by an authority listed in Appendix 2.

6. "Regulatory System" means the body of legal requirements for Good Manufacturing Practices, inspections, and enforcements that ensure public health protection and legal authority to assure adherence to these requirements.

Article 2

Purpose

The provisions of this Annex govern the exchange between the Parties and normal endorsement by the receiving authority of official Good Manufacturing Practices (GMPs) inspection reports after a transitional period aimed at determination of the equivalence of the regulatory systems of the Parties, which is the cornerstone of this Annex.

Article 3

Scope

The provisions of this Annex shall apply to pharmaceutical inspections carried out in the United States and Member States of the European Community before products are marketed (hereafter referred to as "pre-approval inspections") as well as during their marketing (hereafter referred to as "post-approval inspections").

Appendix 1 names the laws, regulations and administrative provisions governing these inspections and the GMPs requirements.

Appendix 2 lists the authorities participating in activities under this Annex.

Articles 6, 7, 8, 9, 10 and 11 of the Agreement do not apply to this Annex.

Article 4

Product coverage

These provisions will apply to medicinal products for human or animal use, intermediates and starting materials (as referred to in the EC) and to drugs for human or animal use, biological products for human use, and active pharmaceutical ingredients (as referred to in the United States), only to the extent they are regulated by the authorities of both Parties as listed in Appendix 2.

Human blood, human plasma, human tissues and organs, and veterinary immunologicals are excluded from the scope of this Annex. Human plasma derivatives (such as immunoglobulins and albumin), investigational medicinal products/new drugs, human radiopharmaceuticals and medicinal gases are also excluded during the transition phase, their situation will be reconsidered at the end of the transition period. Products regulated by the Center for Biologics Evaluation and Research as devices are not covered under this Annex.

Appendix 3 contains an indicative list of products covered by this Annex.

CHAPTER 2

TRANSITION PERIOD

Article 5

Length of transition period

A three-year transition period will start immediately after the effective date of the Agreement.

Article 6

Equivalence assessment

1. The criteria to be used by the Parties to assess equivalence are listed in Appendix 4. Information pertaining to the criteria under Community competence will be provided by the Community.

2. The authorities of the parties will establish and communicate to each other their draft programmes for assessing the equivalence of the respective regulatory systems in terms of quality assurance of the products and consumer protection. These programmes will be carried out, as deemed necessary by the authorities, for post- and pre-approval inspections and for various product classes or processes.

3. The equivalence assessment shall include information exchanges (including inspection reports), joint training, and joint inspections for the purpose of assessing regulatory systems and the authorities' capabilities. In conducting the equivalence assessment, the Parties will ensure that efforts are made to save resources.

4. Equivalence assessment for authorities added to Appendix 2 after the effective date of this agreement will be conducted as described in this Annex, as soon as practicable.

Article 7

Participation in the equivalence assessment and determination

The authorities listed in Appendix 2 will actively participate in these programs to build a sufficient body of evidence for their equivalence determination. Both parties will exercise good faith efforts to complete equivalence assessment as expeditiously as possible to the extent the resources of the authorities allow.

Article 8

Other transition activities

As soon as possible, the authorities will jointly determine the essential information which must be present in inspection reports and will cooperate to develop mutually agreed inspection report format(s).

CHAPTER 3

END OF TRANSITION PERIOD

Article 9

Equivalence determination

Equivalence is established by having in place regulatory systems covering the criteria referred to in Appendix 4, and a demonstrated pattern of consistent performance in accordance with these criteria. A list of authorities determined as equivalent shall be agreed to by the Joint Sectoral Committee at the end of the transition period, with reference to any limitation in terms of inspection type (e.g. post-approval or pre-approval) or product classes or processes.

The Parties will document insufficient evidence of equivalence, lack of opportunity to assess equivalence or a determination of non-equivalence, in sufficient detail to allow the authority being assessed to know how to attain equivalence.

Article 10

Authorities not listed as currently equivalent

Authorities not currently listed as equivalent, or not equivalent for certain types of inspections, product classes or processes may apply for reconsideration of their status once the necessary corrective measures have been taken or additional experience is gained.

CHAPTER 4

OPERATIONAL PERIOD

Article 11

Start of the operational period

The operational period shall start at the end of the transition period and its provisions apply to inspection reports generated by authorities listed as equivalent for the inspections performed in their territory.

In addition, when an authority is not listed as equivalent based on adequate experience gained during the transition period, the Food and Drug Administration (FDA) will accept for normal endorsement (as provided in Article 12) inspection reports generated as a result of inspections conducted jointly by that authority on its territory and another authority listed as equivalent, provided that the authority of the Member State in which the inspection is performed can guarantee enforcement of the findings of the inspection report and require that corrective measures be taken when necessary. FDA has the option to participate in these inspections, and based on experience gained during the transition period, the Parties will agree on procedures for exercising this option.

In the EC, the qualified person will be relieved of responsibility for carrying the controls laid down in Article 22 paragraph 1(b) of Council Directive 75/319/EEC provided that these controls have been carried out in the United States and that each batch/lot is accompanied by a batch certificate (in accordance with the WHO certification scheme on the quality of medicinal products) issued by the manufacturer certifying that the product complies with requirements of the marketing authorization and signed by the person responsible for releasing the batch/lot.

Article 12

Nature of recognition of inspection reports

Inspection reports (containing information as established under Article 8), including a GMP compliance assessment, prepared by authorities listed as equivalent, will be provided to the authority of the importing Party. Based on the determination of equivalence in light of the experience gained, these inspection reports will normally be endorsed by the authority of the importing Party, except under specific and delineated circumstances. Examples of such circumstances include indications of material inconsistencies or inadequacies in an inspection report, quality defects identified in the post-market surveillance or other specific evidence of serious concern in relation to product quality or consumer safety. In such cases, the authority of the importing Party may request clarification from the authority of the exporting Party which may lead to a request for re-inspection. The authorities will endeavour to respond to requests for clarification in a timely manner.

Where divergence is not clarified in this process, an authority of the importing country may carry out an inspection of the production facility.

Article 13

Transmission of post-approval inspection reports

Post-approval GMP inspection reports concerning products covered by this Annex will be transmitted to the authority of the importing country within 60 calendar days of the request. Should a new inspection be needed, the inspection report will be transmitted within 90 calendar days of the request.

Article 14

Transmission of pre-approval inspection reports

A preliminary notification that an inspection may have to take place will be made as soon as possible.

Within 15 calendar days, the relevant authority will acknowledge receipt of the request and confirm its ability to carry out the inspection. In the EC, requests will be sent directly to the relevant authority, with a copy to the European Agency for the Evaluation of Medicinal Products (EMEA). If the authority receiving the request cannot carry out the inspection as requested, the requesting authority shall have the right to conduct the inspection.

Reports of pre-approval inspections will be sent within 45 calendar days of the request that transmitted the appropriate information and detailed the precise issues to be addressed during the inspection. A shorter time may be necessary in exceptional cases and these will be described in the request.

Article 15

Monitoring continued equivalence

Monitoring activities for the purpose of maintaining equivalence shall include review of the exchange of inspection reports and their quality and timeliness; performance of a limited number of joint inspections and the conduct of common training sessions.

Article 16

Suspension

Each Party has the right to contest the equivalence of an authority. This right will be exercised in an objective and reasoned manner in writing to the other Party.
The issue shall be discussed in the Joint Sectoral Committee promptly upon such notification. Where the JSC determines that verification of equivalence is required, it may be carried out jointly by the Parties in a timely manner, pursuant to Article 6.

Efforts will be made by the Joint Sectoral Committee to reach unanimous consent on the appropriate action. If agreement to suspend is reached in the Joint Sectoral Committee, an authority may be suspended immediately thereafter. If no agreement is reached in the Joint Sectoral Committee, the matter is referred to the Joint Committee. If no unanimous consent is reached within 30 days after such notification, the contested authority will be suspended.

Upon the suspension of an authority previously listed as equivalent, a Party is no longer obligated to normally endorse the inspection reports of the suspended authority. A Party shall continue to normally endorse the inspection reports of that authority prior to suspension, unless the authority of the receiving party decides otherwise based on health or safety considerations. The suspension will remain in effect until unanimous consent has been reached by the Parties on the future status of that authority.

CHAPTER 5

JOINT SECTORAL COMMITTEE

Article 17

Role and composition of the Joint Sectoral Committee

A Joint Sectoral Committee is set up to monitor the activities under both the transitional and operational phases of this Annex.

The Committee will be co-chaired by a representative of FDA for the U.S. and a representative of the EC who each will have one vote. Decisions will be taken by unanimous consent.

The Joint Sectoral Committee's functions will include:

1. making a joint assessment, which must be agreed by both Parties, of the equivalence of the respective authorities,

2. developing and maintaining the list of equivalent authorities, including any limitation in terms of inspecting type or products, and communicating the list to all authorities and the Joint Committee,

3. providing a forum to discuss issues relating to this Annex, including concerns that an authority may be no longer equivalent and opportunity to review product coverage,

4. consideration of the issue of suspension.

The Joint Sectoral Committee shall meet at the request of either Party and, unless the co-chairs otherwise agree, at least once each year. The Joint Committee will be kept informed of the agenda and conclusions of meetings of the Joint Sectoral Committee.

CHAPTER 6

INFORMATION EXCHANGE

Article 18

Regulatory collaboration

The Parties and authorities shall inform and consult one another, as permitted by law, on proposals to introduce new controls or to change existing technical regulations or inspection procedures and to provide the opportunity to comment on such proposals.

The Parties shall notify each other in writing of any changes to Appendix 2.

Article 19

Information relating to quality aspects

The authorities will establish an appropriate means of exchanging information on any confirmed problem reports, corrective actions, recalls, rejected import consignments and other regulatory and enforcement problems for products subject to this Annex.

Article 20

Alert System

The details of an alert system will be developed during the transitional period. The system will be maintained in place at all times. Elements to be considered in developing such a system are described in Appendix 5.

Contact points will be agreed between both Parties to permit authorities to be made aware with the appropriate speed in case of quality defect, recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the product.

CHAPTER 7

SAFEGUARD CLAUSE

Article 21

Each Party recognizes that the importing country has a right to fulfil its legal responsibilities by taking actions necessary to ensure the protection of human and animal health at the level of protection it deems appropriate. This includes the suspension of the distribution, product detention at the border of the importing country, withdrawal of the batches and any request for additional information or inspection as provided in Article 12.

APPENDIX 1

List of applicable laws, regulations 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 proprietary medicinal products, as extended, widened and amended.

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/C 63/03).

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

For the United States:

Relevant sections of the United States Federal Food, Drug, and Cosmetic Act and the United States Public Health Service Act.

Relevant sections of Title 21, United States Code of Federal Regulations (CFR) Parts 1-99, Parts 200-299, Parts 500-599, and Parts 600-799.

Relevant sections of the FDA Investigations Operations Manual, the FDA Regulatory Procedures Manual, the FDA Compliance Policy Guidance Manual, the FDA Compliance Program Guidance Manual, and other FDA guidances.

APPENDIX 2

List of Authorities

United States:

In the United States, the regulatory authority is the Food and Drug Administration.

European Community:

In the European Community, the regulatory authorities are the following:

BELGIUM	Inspection générale de la Pharmacie Algemene Farmaceutische Inspectie
DENMARK	Laegemiddelstyrelsen
GERMANY	Bundesministerium für Gesundheit for immunologicals: Paul-Ehrlich-Institut, Federal Agency for Sera & Vaccines
GREECE	.ΠΥΘΡδΖ 8ΨΚΙΥΘ[ΤδΖ >ΙΨΤΔΡΩ] Ministry of Health and Welfare National Drug Organization (E.O.F.)

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) Dirección General de la Producción Agraria
FRANCE	for medicinal products for human use: Agence du Médicament for veterinary medicinal products: Agence Nationale du Médicament Vétérinaire
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	Instituto da Farmácia e do Medicamento ⇨ INFARMED
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)

APPENDIX 3

Indicative list of Products covered by the Sectoral Annex

Recognizing that precise definition of medicinal products and drugs are to be found in the legislation referred to above, an indicative list of products covered by the agreement is given below:

- human medicinal products including prescription and non-prescription drugs;
- human biologicals including vaccines, and immunologicals;
- veterinary pharmaceuticals, including prescription and non-prescription drugs, with the exclusion of veterinary immunologicals;
- pre-mixes for the preparation of veterinary medicated feeds (EC), Type A medicated articles for the preparation of veterinary medicated feeds (US);
- intermediate products and active pharmaceutical ingredients or bulk pharmaceuticals (US)/starting materials (EC).

APPENDIX 4

Criteria for Assessing Equivalence for Post- and Pre-Approval

I. Legal/Regulatory authority and structures and procedures providing for post- and pre-approval:

A. Appropriate statutory mandate and jurisdiction.

B. Ability to issue and update binding requirements on GMPs and guidance documents.

C. Authority to make inspections, review and copy documents, and to take samples and collect other evidence.

D. Ability to enforce requirements and to remove products found in violation of such requirements from the market.

E. Substantive current good manufacturing requirements.

F. Accountability of the regulatory authority.

G. Inventory of current products and manufacturers.

H. System for maintaining or accessing inspection reports, samples and other analytical data, and other firm/product information relating to matters covered by this Sectoral Annex.

II. Mechanisms in place to assure appropriate professional standards and avoidance of conflicts of interest.

III. Administration of the regulatory authority:

A. Standards of education/qualification and training.

B. Effective quality assurance systems measures to ensure adequate job performance.

C. Appropriate staffing and resources to enforce laws and regulations.

IV. Conduct of Inspections:

A. Adequate pre-inspection preparation, including appropriate expertise of investigator/team, review of firm/product and databases, and availability of appropriate inspection equipment.

B. Adequate conduct of inspection, including statutory access to facilities, effective response to refusals, depth and competence of evaluation of operations, systems and documentation; collection of evidence; appropriate duration of inspection and completeness of written report of observations to firm management.

C. Adequate post-inspection activities, including completeness of inspectors' report, inspection report review where appropriate, and conduct of follow-up inspections and other activities where appropriate, assurance of preservation and retrieval of records.

V. Execution of regulatory enforcement actions to achieve corrections, designed to prevent future violations, and to remove products found in violation of requirements from the market.

VI. Effective Use of Surveillance Systems:

A. Sampling and analysis.

B. Recall monitoring.

C. Product defect reporting system.

D. Routine surveillance inspections.

E. Verification of approved manufacturing process changes to marketing authorizations/approved applications.

VII. Additional specific criteria for pre-approval inspections

A. Satisfactory demonstration through a jointly developed and administered training program and joint inspections to assess the authorities' capabilities.

B. Pre-inspection preparation includes the review of appropriate records, including site plans and drug master file or similar documentation to enable adequate inspections.

C. Ability to verify chemistry, manufacturing and control data supporting an application is authentic and complete.

D. Ability to assess and evaluate research and development data as scientifically sound, especially transfer technology of pilot, scale up and full scale production batches.

E. Ability to verify conformity of the on site processes and procedures with those described in the application.

F. Review and evaluate equipment installation, operational and performance qualification data, and evaluate test method validation.

APPENDIX 5

Elements to be Considered in Developing a Two-way Alert System

1. Documentation

- Definition of a crisis/emergency and under what circumstances an alert is required
- Standard Operating Procedures (SOPs)
- Mechanism of health hazards evaluation and classification
- Language of communication and transmission of information

2. Crisis Management System

- Crisis analysis and communication mechanisms
- Establishment of contact points
- Reporting mechanisms

3. Enforcement Procedures

- Follow-up mechanisms
- Corrective action procedures

4. Quality Assurance System

- Pharmacovigilance programme
- Surveillance/monitoring of implementation of corrective action

5. Contact points

For the purpose of this agreement, the contact points for the alert system will be:

for the European Community:
the Executive Director of the European Agency for the Evaluation of Medicinal Products, 7, Westferry Circus, Canary Wharf, UK London E14 4HB, England. Telephone +44-171-418 8400, Fax 418 8416.

for the United States:
(to be provided by the U.S.)