COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 30.11.2000
COM(2000) 741 final

2000/0302 (ACC)
2000/0303 (ACC)

Proposal for a

COUNCIL DECISION

on the signature on behalf of the Community of an additional Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Hungary, of the other part on Conformity Assessment and Acceptance of Industrial Products

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on the conclusion of an additional Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Hungary, of the other part on Conformity Assessment and Acceptance of Industrial Products

(presented by the Commission)

EXPLANATORY MEMORANDUM

I. EXPLANATORY MEMORANDUM

On the basis of negotiating directives adopted by the Council on 21.9.92 and of the specific decision issued by the Council in June 1997 addressing guidelines to the Commission for the negotiation of European Conformity Assessment Agreements with Central and Eastern European Countries, the Commission has negotiated and initialled an additional protocol to the Europe Agreement with Hungary (**P**rotocol to the **E**urope Agreement on **C**onformity assessment and **A**cceptance of industrial products, hereinafter referred to as "**PECA**").

The text of this Protocol is attached to this Communication. The following provides an assessment of the Protocol in the light of the negotiating directives approved by the Council, and proposes that the Council authorises the signature of the additional Protocol to the Europe Agreement and decides to approve its conclusion on behalf of the Community.

I.1 ASSESSMENT OF THE AGREEMENT

Considering that this agreement is intended to work only during the pre-accession period, and that an appropriate legal framework was offered by the Europe Agreement, it was decided, in consultation with the 133 Committee, to adopt this agreement as a Protocol to the Europe Agreement rather than an stand alone agreement as foreseen previously.

The draft PECA follows the general principles laid down in the Commission's communication on Community External Trade Policy in the field of standards and conformity assessment[1] under its paragraph 49.

The PECA provides for an extension of certain benefits of the Internal Market in sectors already aligned. The PECA thus facilitates market access by eliminating technical barriers to trade with respect to industrial products. To this end, the PECA provides for two mechanisms, a) for the mutual acceptance of industrial products which fulfil the requirements to be lawfully placed on the market in one of the Parties, and b) the mutual recognition of the results of conformity assessment of industrial products subject to Community law and to the equivalent national law.

The first mechanism, i.e. the mutual acceptance of industrial products, confirms that Articles 9.4 and 10.4 of the Europe Agreement with Hungary apply without other restriction as referred to in Article 35 of the Europe Agreement. This provision adds the predictability that is necessary to manufacturers and exporters, confirming in advance that industrial products under this mechanism may freely move between the Parties. The annexes making this mechanism operational have still to be negotiated.

The second mechanism is a particular type of mutual recognition agreement (MRA) in which the mutual recognition operates on the basis of the *acquis communautaire*. It allows industrial products certified by Notified Bodies in the European Union to be placed on the Hungarian market without having to undergo any further approval procedures, and vice-versa. The following sectors are covered: machinery, electrical safety, electromagnetic compatibility, gas appliances, hot water boilers, medical devices, good laboratory practice (GLP) for medicinal

[1] COM (96) 564 - final. 13.11.96.

products for human use and medicinal products good manufacturing practice (GMP) inspection and batch certification.

Hungary has taken over the Community technical legislation in the sectors covered by the Protocol and participates in the European organisations in the field of standards, metrology, testing laboratories and accreditation.

The PECA consists of a framework agreement and a series of annexes as referred to above. A unilateral Community declaration inviting the Hungarian representatives to experts meetings and committees established under the Community law referred to in the annexes is attached to the Final Act, making it clear that this will not entail any participation in the Community decision-making process. An assessment of the PECA is made in the next paragraphs.

I.1.1 Framework Agreement

An article-by-article assessment follows:

Pre-amble. This sets out the basic objective of the PECA which is that, as the application for membership of the European Union implies the implementation of the *acquis communautaire* by the applicant country, it provides the opportunity to extend certain benefits of the Single Market in certain sectors already aligned before.

Article 1: Purpose. This article establishes the purpose of the PECA, namely the elimination of technical barriers to trade in respect to industrial products. The PECA provides for two mechanisms, a) for the mutual acceptance of industrial products which fulfil the requirements to be lawfully placed on the market in one of the Parties, and b) the mutual recognition of the results of conformity assessment of industrial products subject to Community law and to the equivalent national law.

Article 2: Definitions. This is self-explanatory. Definitions of industrial products, Community and national law have been included. All pieces of legislation and implementation measures (administrative provisions, guidelines and other means of implementation of the legislation) are covered by the definitions of Community and national law.

Article 3: Alignment of legislation. This contains a commitment for Hungary to take appropriate measures in order to maintain or complete the take-over of Community law, namely in the field of technical legislation and for the purpose of the PECA. Together with the 4th whereas, it means that the alignment is an ongoing process and the Parties agree to iron out any problems of transposition that could appear later.

Article 4: Mutual acceptance of industrial products. The principle under Article 1.1) is detailed in this article. It provides that listing industrial products in such annexes will confirm that these products can freely circulate between the Parties. As already stated, no such annex has been negotiated yet.

Article 5: Mutual recognition of the results of conformity assessment procedures. This provision expands the principle under Article 1.2). This kind of recognition is similar to the one in Mutual Recognition Agreements, with the special feature that all legislation and standards are aligned. The sectoral annexes will contain the references to the relevant Community and national legislation.

Article 6: Safeguard clause. This sets up the right of each Party to deny market access when such Party is able to demonstrate that a product might endanger the legitimate concern which is protected by legislation listed in the annexes (safety and/or public health of users or other persons mainly). The annexes provide for the detailed procedures to be used in such cases.

Article 7: Extension of coverage. The Parties may modify the scope and coverage of this Protocol through an amendment of the annexes or by the addition of new annexes as soon as all alignment conditions are met.

Article 8: Origin. This provides that the Protocol will apply to industrial products originating in the Parties according to non-preferential rules of origin. This origin can be certified by presentation of a certificate of origin or by a proof of origin according to Protocol 4 of the Europe Agreement.

Article 9: Obligations of Parties as regards their authorities and bodies. This article obliges the Parties to ensure that their respective authorities continuously monitor the technical competence and compliance of the notified bodies and have the necessary power and expertise for designating, suspending, and withdrawing their bodies. In addition, it obliges the Parties to ensure that their respective notified bodies continuously comply with the requirements of Community or national law and maintain their technical competence to carry out the tasks for which they have been notified.

Article 10: Notified bodies. This describes the procedure for the notification of bodies to assess conformity in relation to the legal requirements specified in the corresponding annexes. The procedure is simplified and similar to the one applied within the Community. The second paragraph sets out the procedure for the removal of notified bodies.

Article 11: Verification of notified bodies. This article gives the right to one Party to request a verification of a body notified by the other Party. The verification may be done either by the authorities which have designated the body or together by the authorities of both Parties. If the Parties do not agree on appropriate steps to take, they may notify the Chair of the Association Council of their dissent, and leave to the Association Council to decide on appropriate action. The notified body would then be suspended from the notification of the Association Council until a final decision is taken.

Article 12: Exchange of information. A transparency provision to ensure a correct and uniform application and interpretation of the Protocol. The Parties are advised to encourage their bodies to cooperate in order to establish mutual recognition agreements in the voluntary sphere.

Article 13: Confidentiality. A classical provision to avoid disclosing information acquired under this Protocol.

Article 14: Management of the Protocol. The Association Council will be responsible for its effective functioning and may delegate its duties in conformity with the relevant Articles of the Europe Agreement.

Article 15: Technical cooperation and assistance. This confirms the Community policy on technical cooperation and assistance with a view to properly implementing this Protocol.

Article 16: Agreements with other countries. This confirms that, unless otherwise agreed, the PECA does not entail any obligation, for one Party, to accept conformity assessments

carried out in another country, even if there is an agreement on recognition of conformity assessment between the other Party and any other third country.

Article 17: Entry into force. This is a standard provision that provides the arrangement for the entry into force.

Article 18: Status of the Protocol. This establishes the fact that the PECA is an integral part of the Europe Agreement.

I.1.2 The Annexes to the Protocol

I.1.2.1 Annexes on Mutual Recognition of Results of Conformity Assessment

There follows an assessment of the content of the annexes in terms of their coverage, and other implications where relevant. In making this assessment, the Commission has kept in mind the following elements:

a) the overall consistency with the Community policy objectives in the field of standardisation, certification and conformity assessment for the sectors and industrial products covered;

b) the overall consistency with Community policy objectives in the field of the removal of technical barriers to trade;

The sectoral assessment is followed in item I.2 by an overall appreciation of the benefits of the Protocol.

Annexes on Machinery, Electrical Safety, Electromagnetic Compatibility, Hot Water Boilers, Gas Appliances and Medical Devices.

These annexes on mutual recognition of results of conformity assessment cover a range of industrial products subject to third party conformity assessment under the New Approach Directives in the relevant sectors All these annexes present the same structure.

Coverage is determined by the relevant Community or national law, listed under *Section I* of each annex. *Section II*, on notifying authorities, lists the authorities responsible for the designation of bodies in the Member Sates and Hungary. *Section III*, on notified bodies, makes reference to the notification of all Conformity Assessment Bodies notified by the Member States and by Hungary. *Section IV*, on specific arrangements, fixes the two procedures for the safeguard clause, relating to industrial products and to harmonised standards.

In the medical devices annex, *Section IV* includes three additional provisions which provide for the registration of the person responsible for placing devices on the market, for the labelling of medical devices and for specific exchanges of information between the Parties.

Annex on good laboratory practice (GLP) for medicinal products.

This annex establishes the mutual recognition of each Party's compliance monitoring programmes on good laboratory practice (GLP) that are in accordance with the OECD decisions and recommendations, and the mutual acceptance of studies, data generated, study audits and test facility inspections of the other Party.

The Parties also recognise the equivalence of each other's compliance monitoring programmes. Recognition of inspection results and the ensuing compliance with the GLP principles remove the need for companies in each Party to be inspected by the authorities of the other Party. Both Parties have accepted the decisions and recommendations of the OECD Council on the definition of terms and on compliance monitoring procedures for Good Laboratory Practice.

This annex applies to the non-clinical testing of medicinal products, being either substances or preparations, which are explicitly covered by the legislative, regulatory and administrative requirements, listed in *Section I*.

In this annex, "notified test facilities" means the test facilities recognised under each Party's GLP monitoring programme. *Section II*, on notified test facilities, establishes the notification procedure of test facilities for which GLP compliance has been established. The Notifying Authorities listed in *Section III* are the GLP monitoring authorities of each Member State and Hungary.

Section IV, on specific arrangements, contains clauses on test facility inspections, safeguard mechanisms, and cooperation between the Parties.

This annex will enter into operation upon decision of the Association Council. This decision will be taken in light of the Mutual Joint Visits (MJV) carried out in Hungary according to the OCDE Pilot Project on Examination of National GLP Compliance Monitoring Programmes.

The Annex gives industry the necessary predictability in terms of acceptance of their data and removes needless duplication of inspections.

Annex on medicinal products GMP inspection and batch certification

This annex establishes the mutual recognition of the conclusions of each Party's Good Manufacturing Practice (GMP) inspections, of each Party's manufacturing authorisations, and of manufacturers' batch certificates. All medicinal products for human use are covered.

Section I lists the relevant Community and national law. Section II lists the official GMP inspection services of each Member State and Hungary.

Section III include provisions concerning common definitions of terms in conformity with their respective legislation, and the scope and coverage of this annex. A pre-operational phase of 6 months is foreseen. The Association Council will decide on its termination or prolongation. The operation of this Annex will start immediately after the successful termination of the pre-operational phase.

Additional provisions include mechanisms for cooperation (transmission of reports, exchange of information, training of inspectors, joint inspections, alert system, contact points) between the respective inspection authorities. A safeguard clause for inspections is included to reserve each Party's right to conduct exceptionally its own inspections for reasons identified in advance to the other Party. The Parties are supposed to use their best endeavours to resolve any divergence of views which could occur. Unresolved divergences of views may be referred to the Association Council.

This Annex will remove the need for duplicating batch release procedures and thus save important analysis costs for each imported batch. In addition, recognition of inspections will

permit to avoid duplication inspections by authorities. This should lead to important savings in terms of time to access the market and other fees and inspection costs.

I.1.2.2 Annexes on Mutual Acceptance of Industrial Products

No such annexes have been negotiated for the moment. The PECA, in line with the Europe Agreement, provides nevertheless the basis for such acceptance of products, similar to the one which operates in the Community.

I.1.2.3 Unilateral Declaration

This is attached to the Final Act and is annexed to this Communication.

a) Unilateral Community Declaration relating to attendance of the Hungarian representatives to Committees. Through this declaration, Hungary is invited to send observers to the meetings of the Committees established or referred to under the Community legislation included in the annexes. This declaration follows the principles of the Commission Communication on "Participation of candidate countries in Community programmes, agencies and committees"[2].

I.1.3 Relations with EFTA /EEA Member Countries

In accordance with the general information and consultation procedures set out in the European Economic Area-Agreement and Protocol 12 of that Agreement, the Commission kept EFTA/EEA Member Countries regularly informed on the progress of the negotiations and informed them on the final result thereof. The EFTA/EEA Member Countries are in the initial stage of negotiating a parallel mutual recognition agreement with Hungary.

I.2 OVERALL APPRECIATION

The Commission considers that the proposed PECA creates an acceptable balance of benefits for all parties in the pre-accession framework. In all sectors the Community has secured effective market access - in terms of access to all mandatory procedures of the other party. The PECA confirms that Hungary has taken over the Community legislation in certain sectors before its accession. Both political and commercial benefits are achieved with the PECA.

The Protocol will allow Community exporters, if they so choose, to test and certify their industrial products to the same (aligned) requirements prior to export, and then access that market without any further conformity assessment requirements. The certification procedures will only need to be carried out one time for both markets and against the same aligned requirements or standards. The recognition of certification will permit savings and stimulate exports. European industry federations were consulted and supported unequivocally the Protocol.

Industrial groups, while supporting the Protocol, have not always been able to quantify the costs or time taken to obtain conformity assessment of their industrial products in Hungary. The precise extent of savings in time, cost and market opportunity of this Protocol is therefore not feasible in every case to determine. This may only be possible once the Protocol has been in operation for some time. However, on the basis of a rough calculation, it is estimated[3] that

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[2] Point 4.2.b). COM (99) 710 - final. 20.12.1999.

[3] Working hypothesis that certification and other related costs amount to an average of 1% of trade.

this Protocol would create cost saving opportunities for the exporting industry of around € 67 millions and about € 83 millions in terms of cost savings to exporters to the EC, some part of which will be passed on to European importers and consumers.

Trade figures between the EC and Hungary are attached for information. The general trade balance in sectors covered by this Protocol shows a trade surplus for Hungary (factor of 1,2:1, varying from 1,4:1 in the machinery sector to 1,1:1 in the electrical sector). However, there are sectors such as pharmaceuticals, gas appliances and medical devices where the Community has a trade surplus with Hungary (factors of 5,7:1, 22:1 and 1,9:1). It is expected that trade will increase further when the PECA is in force.

In fact, most benefits are clearly not quantifiable, such as reduced time for accessing markets, better predictability, less protectionism, and harmonisation of systems. What can be ascertained is that any agreement provides reciprocal levels of market access, in terms of conformity assessment.

These advantages outweigh greatly the resources that the Commission will have to engage in maintenance activities of the Protocol, evaluated at 1.6 person per year and some travel and other expenses relating to meetings and other activities such as editing guides.

In terms of the benefits to Hungary, the PECA will facilitate access to the Community market and will give political credit for having aligned its legislation. Hungary regards the PECA as a means to develop closer industrial relations with the EU and fully to integrate certain sectors with the Single Market before accession.

II. THE DRAFT COUNCIL DECISIONS

A proposal for two Council decisions is attached.

The first one is concerned with the signature of the Protocol. Signature is required by Hungary for the adoption of this Protocol. It is accordingly proposed that the President of the Council be authorised to designate the person empowered to sign the Protocol on behalf of the Community, subject to conclusion later, on the basis of Articles 133 and 300 of the Treaty.

The proposal for a second decision is concerned with the adoption of the PECA. In this context, the Council should, in line with the previous Council decisions on the conclusion of mutual recognition agreementsestablish the appropriate Community procedure for the implementation and management of the Protocol.

In particular, the Council should confer on the Commission, after consultations with the special committee appointed by the Council, the necessary powers for the management and implementation of the Protocol. Moreover, the Council should delegate to the Commission, acting in consultation with the special committee, the necessary powers to determine in certain cases the Community position with regard to this Protocol in the Association Council, or where applicable the Association Committee.

In all other cases the Community position with respect to the Protocol shall be determined by the Council, acting by qualified majority, on a proposal from the Commission.

The Commission therefore proposes that the Council adopts the attached decision on the signature and conclusion of the PECA.

2000/0302 (ACC)

Proposal for a

COUNCIL DECISION

on the signature on behalf of the Community of an additional Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Hungary, of the other part on Conformity Assessment and Acceptance of Industrial Products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133, in conjunction the first sentence of the first subparagraph of Article 300 (2) thereof,

Having regard to the proposal from the Commission[4],

Whereas:

(1) The Europe Agreement establishing an association between the European Communities and their Member States, of the one part, and the Republic of Hungary of the other part[5], entered into force on 1 February 1994.

(2) Article 73(2) of the Europe Agreement provides that co-operation in the fields of standardisation and conformity assessment shall seek to achieve the conclusion of agreements on mutual recognition.

(3) The Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products has been negotiated by the Commission on behalf of the Community.

(4) Subject to its possible conclusion at a later date, the Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products initialled in Brussels on 10 July 2000 should be signed,

HAS DECIDED AS FOLLOWS:

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4 OJ C …, …, p. …

5 OJ L 347, 31.12.1993, p.2.

Sole Article

Subject to a possible conclusion at a later date, the President of the Council is hereby authorised to designate the person empowered to sign, on behalf of the Community, the Protocol to the Europe Agreement with Hungary on Conformity Assessment and Acceptance of Industrial Products.

Done at Brussels, […]

For the Council
The President
[…]

2000/0303 (ACC)

Proposal for a

COUNCIL DECISION

on the conclusion of an additional Protocol to the Europe Agreement establishing an Association between the European Communities and their Member States, of the one part, and the Republic of Hungary, of the other part on Conformity Assessment and Acceptance of Industrial Products

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 in conjunction Article 300 paragraph 2, first subparagraph, first sentence, paragraph 3, first subparagraph, first sentence, and paragraph 4 thereof,

Having regard to the proposal from the Commission[6],

Whereas:

(1) The Europe Agreement establishing an association between the European Communities and their Member States, of the one part, and the Republic of Hungary of the other part[7], entered into force on 1 February 1994.

(2) Article 73(2) of the Europe Agreement provides that co-operation in the fields of standardisation and conformity assessment shall seek to achieve the conclusion of agreements on mutual recognition.

(3) Article 108 of the Europe Agreement provides that the Association Council may delegate to the Association Committee any of its powers.

(4) Article 2 of Decision 93/742/EEC of the Council and the Commission of 13 December of 1993 on the conclusion of the Europe Agreement between the European Communities and their Member States, of the one part, and the Republic of Hungary, of the other part[8], provides for the Community decision-making procedures and for the presentation of the Community position in the Association Council and in the Association Committee.

(5) Article 14 of Decision No 1/94 of the Association Council between the European Communities and their Member States, of the one part, and the Republic of Hungary, of the other part of 7 March 1994 on its rules of procedure[9] provides that the Association Committee may set up further subcommittees or groups to assist in carrying out its duties.

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6 OJ C …, …, p. …
7 OJ L 347, 31.12.1993, p.2.
8 OJ L 347, 31.12.1993, p.1.
9 OJ L 242, 17.9.1994, p. 23.

(6) The draft Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products, has been signed in Brussels on [… 2000] on behalf of the Community, and should be approved.

(7) Certain tasks for implementation have been attributed to the Association Council and in particular the power to amend certain aspects of the annexes.

(8) The appropriate internal procedures should be established to ensure the proper functioning of the Protocol, and

(9) It is necessary to empower the Commission to make certain technical amendments to this Protocol and to take certain decisions for its implementation,

HAS DECIDED AS FOLLOWS:

Article 1

The additional Protocol to the Europe Agreement with the Republic of Hungary on Conformity Assessment and Acceptance of Industrial Products between the European Community and the Republic of Hungary (hereinafter "the Protocol"), is hereby approved on behalf of the European Community.

The text of the Protocol is attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Community, transmit the diplomatic note provided for in Article 17 of the Protocol[10].

Article 3

1. The Commission, after consultation with the special committee appointed by the Council, shall:

   (a) proceed to the notifications, acknowledgements, suspensions and withdrawals of bodies, and appointments of joint team or teams of experts, in accordance with Articles 10, 11 and 14, indent c) of the Protocol, and Section IV of the Good Laboratory Practice (GLP) annex and Section III of the Good Manufacturing Practice (GMP) annex to the Protocol;

   (b) make the consultations, exchange of information, the requests for verifications and for participation in verifications, in accordance with Articles 3, 12 and 14, indents d) and e), Section II of the Good Laboratory Practice (GLP) annex to this Protocol, and Sections III and IV of the annexes to the Protocol concerning machinery, electrical safety, electromagnetic compatibility, hot water boilers, gas appliances, medical devices, good laboratory practice (GLP), and good manufacturing practice (GMP);

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[10] The date of entry into force of the Protocol will be published in the *Official Journal of the European Communities* by the General Secretariat of the Council.

(c) if necessary, reply to requests in accordance with Article 11, Sections III and IV of the annexes to the Protocol concerning machinery, electrical safety, electromagnetic compatibility, hot water boilers, gas appliances, medical devices, good laboratory practice (GLP), and good manufacturing practice (GMP).

2. The position to be taken by the Community in the Association Council, and where applicable in the Association Committee, shall be determined by the Commission, following consultation of the special committee referred to in paragraph 1 of this Article, with regard to:

(a) Amendments of the annexes in accordance with Article 14, indent a) of the Protocol;

(b) Any decisions regarding disagreements on the results of the verifications and the suspensions, in part or totally, of any notified body in accordance with Article 11, paragraphs 2 and 3 of the Protocol;

(c) Any measures taken in the application of the safeguard clauses in Section IV of the annexes of the Protocol concerning machinery, electrical safety, electromagnetic compatibility, hot water boilers, gas appliances, medical devices, and good laboratory practice (GLP);

(d) The pre-operational phase and the measures to be taken in accordance with paragraphs 3.3, 3.4 and 5.1 of Section III of the Good Manufacturing Practice (GMP) annex of the Protocol;

(e) Any measures concerning the verification, suspension, or withdrawal of industrial products as having mutual acceptance under Article 4 of the Protocol.

3. In all other cases the position to be taken by the Community in the Association Council, and where applicable in the Association Committee, with regard to this Protocol shall be determined by the Council, acting by qualified majority on a proposal from the Commission.

Done at Brussels,

For the Council
The President

ANNEX

PROTOCOL

TO THE EUROPE AGREEMENT ESTABLISHING AN ASSOCIATION BETWEEN THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES, OF THE ONE PART, AND THE REPUBLIC OF HUNGARY, OF THE OTHER PART, ON CONFORMITY ASSESSMENT AND ACCEPTANCE OF INDUSTRIAL PRODUCTS – PECA

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The European Community and Hungary,

hereinafter referred to as "the Parties",

Whereas Hungary has applied for membership of the European Union and such membership implies the effective implementation of the *acquis* of the European Community,

Recognising that the progressive adoption and implementation of Community law by Hungary provides the opportunity to extend certain benefits of the Internal Market and to ensure its effective operation in certain sectors before accession,

Considering that, in the sectors covered by this Protocol, the Hungarian national law substantially takes over the Community law,

Considering their shared commitment to the principles of free movement of goods and to promoting product quality, so as to ensure the health and safety of their citizens and the protection of the environment, including through technical assistance and other forms of co-operation between them,

Desiring to conclude a Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (hereafter the Protocol) providing for the application of the mutual acceptance of industrial products which fulfil the requirements to be lawfully placed on the market in one of the Parties and of the mutual recognition of the results of conformity assessment of industrial products which are subject to Community or national law, noting that Article 73 of the Europe Agreement provides, where appropriate, for the conclusion of an agreement on mutual recognition,

Noting the close relationship between the European Community and Iceland, Liechtenstein and Norway through the Agreement on the European Economic Area, which makes it appropriate to consider the conclusion of a parallel European Conformity Assessment Agreement between Hungary and these countries equivalent to this Protocol,

Bearing in mind their status as Contracting Parties to the Agreement establishing the World Trade Organisation, and conscious in particular of their obligations under the World Trade Organisation Agreement on Technical Barriers to Trade,

HAVE AGREED AS FOLLOWS:

Article 1
Purpose

The purpose of this Protocol is to facilitate the elimination by the Parties of technical barriers to trade in respect of industrial products. The means to this end is the progressive adoption and implementation by Hungary of national law, which is equivalent to Community law.

This Protocol provides for:

1) the mutual acceptance of industrial products, listed in the annexes on "mutual acceptance of industrial products", which fulfil the requirements to be lawfully placed on the market in one of the Parties;

2) the mutual recognition of the results of conformity assessment of industrial products subject to Community law and to the equivalent Hungarian national law, both listed in the annexes on "mutual recognition of results of conformity assessment".

Article 2
Definitions

For the purpose of this Protocol,

"Industrial products" means products, as specified in Article 8 and in Protocol 3 of the Europe Agreement.

“Community law” means any legal act and implementing practice of the European Community applicable to a particular situation, risk or category of industrial products, as interpreted by the Court of Justice of the European Communities.

"National law" means any legal act and implementing practice by which Hungary takes over the Community law applicable to a particular situation, risk or category of industrial products.

The terms used in this Protocol shall have the meaning given in Community law and the Hungarian national law.

Article 3
Alignment of legislation

For the purpose of this Protocol, Hungary agrees to take appropriate measures, in consultation with the European Commission, to maintain or complete the take-over of Community law, in particular in the fields of standardisation, metrology, accreditation, conformity assessment, market surveillance, general safety of products, and producer's liability.

Article 4
Mutual acceptance of industrial products

The Parties agree that, for the purpose of mutual acceptance, industrial products listed in the annexes on "mutual acceptance of industrial products", which fulfil the requirements to be lawfully placed on the market of a Party, may be placed on the market of the other Party, without further restriction. This shall be without prejudice to Article 35 of the Europe Agreement.

Article 5
Mutual recognition of the results of conformity assessment procedures

The Parties agree to recognize the results of conformity assessment procedures carried out in accordance with the Community or national law listed in the annexes on "mutual recognition of the results of conformity assessment". The Parties shall not require procedures to be repeated, nor shall they impose additional requirements, for the purposes of accepting that conformity.

Article 6
Safeguard clause

Where a Party finds that an industrial product placed on its territory by virtue of the present Protocol, and used in accordance with its intended use, may compromise the safety or health of users or other persons, or any other legitimate concern protected by legislation identified in the annexes, it may take appropriate measures to withdraw such a product from the market, to prohibit its placing on the market, putting into service or use, or to restrict its free movement. -The annexes shall provide for the procedure to be applied in such cases.-

Article 7
Extension of coverage

As Hungary adopts and implements further national law taking over Community law, the Parties may amend the annexes or conclude new ones, in accordance with the procedure laid down in Article 14.

Article 8
Origin

The provisions of this Protocol shall apply to industrial products which originate in the Parties according to non-preferential rules of origin. Proof of origin may be demonstrated by a certificate of origin. Such certificate is not required in the case of importation of products covered by a proof of origin according to Protocol 4 of the Europe Agreement.

Article 9
Obligations of Parties as regards their authorities and bodies

The Parties shall ensure that authorities under their jurisdiction which are responsible for the effective implementation of Community and national law shall continuously apply it. Further, they shall ensure that these authorities are able, where appropriate, to notify, suspend, remove suspension and withdraw notification of bodies, to ensure the conformity of industrial products with Community or national law or to require their withdrawal from the market.

The Parties shall ensure that bodies, notified under their respective jurisdiction to assess conformity in relation to requirements of Community or national law specified in the annexes, continuously comply with the requirements of Community or national law.

Further, they shall take all necessary steps to ensure that these bodies maintain the necessary competence to carry out the tasks for which they are notified.

Article 10
Notified bodies

Initially, the bodies notified for the purpose of this Protocol will be those included in the lists which Hungary and the European Community have exchanged before the completion of the procedures for entry into force.

Afterwards, the following procedure shall apply for the notification of bodies to assess conformity in relation to the requirements of Community or national law specified in the annexes:

a) a Party shall forward its notification to the other Party in writing;

b) on the acknowledgement of the other Party, given in writing, the body will be considered as notified and as competent to assess conformity in relation to the requirements specified in the annexes from that date.

If a Party decides to withdraw a notified body under its jurisdiction, it shall inform the other Party in writing. The body will cease to assess conformity in relation to the requirements specified in the annexes from the date of its withdrawal at the latest. Nevertheless, conformity assessment carried out before that date shall remain valid, unless otherwise decided by the Association Council.

Article 11
Verification of notified bodies

Each Party may request the other Party to verify the technical competence and compliance of a notified body under its jurisdiction. Such request will be justified in order to allow the Party responsible for the notification to carry out the requested verification and report speedily to the other Party. The Parties may also jointly examine the body, with the participation of the relevant authorities. To this end, the Parties shall ensure the full co-operation of bodies under their jurisdiction. The Parties shall take all appropriate steps, and use whatever available means may be necessary, with a view to resolving any problems which are detected.

If the problems cannot be resolved to the satisfaction of both Parties, they may notify the chairman of the Association Council of their dissent, giving their reasons. The Association Council may decide on appropriate action.

Unless and until decided otherwise by the Association Council, the notification of the body and the recognition of its competence to assess conformity in relation to the requirements of Community or national law specified in the annexes shall be suspended in part or totally from the date on which the disagreement of the Parties has been notified to the chairman of theAssociation Council.

Article 12
Exchange of information and cooperation

In order to ensure a correct and uniform application and interpretation of this Protocol, the Parties, their authorities and their notified bodies shall:

a) exchange all relevant information concerning implementation of law and practice including, in particular, on procedure to ensure compliance of notified bodies;

b) take part, as appropriate, in the relevant mechanisms of information, co-ordination and other related activities of the Parties;

c) encourage their bodies to co-operate with a view to establishing mutual recognition arrangements in the voluntary sphere.

Article 13
Confidentiality

Representatives, experts and other agents of the Parties shall be required, even after their duties have ceased, not to disclose information acquired under this Protocol which is of the kind covered by the obligation of professional secrecy. This information may not be used for purposes other than those envisaged by this Protocol.

Article 14
Management of the Protocol

Responsibility for the effective functioning of this Protocol shall be held by the Association Council in conformity with Article 106 of the Europe Agreement. In particular, it shall have the power to take decisions regarding:

a) amending the annexes;

b) adding new annexes;

c) appointing a joint team or teams of experts to verify the technical competence of a notified body and its compliance with the requirements;

d) exchanging information on proposed and actual modifications of the Community and national law referred to in the annexes;

e) considering new or additional conformity assessment procedures affecting a sector covered by an annex;

f) resolving any questions relating to the application of this Protocol.

The Association Council may delegate the above responsibilities set out under this Protocol, in conformity with Articles 108 (2) of the Europe Agreement.

Article 15
Technical co-operation and assistance

The European Community may provide technical co-operation and assistance to Hungary where necessary in order to support the effective implementation and application of this Protocol.

Article 16
Agreements with other Countries

Agreements on conformity assessment concluded by either Party with a country which is not a Party to this Protocol shall not entail an obligation upon the other Party to accept the results of conformity assessment procedures carried out in that third country, unless there is an explicit agreement between the Parties in the Association Council.

Article 17
Entry into force

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

Article 18
Status of the Protocol

This Protocol constitutes an integral part of the Europe Agreement.

This Protocol is drawn up in two originals in Hungarian, Danish, Dutch, English, Finnish, French, German, Greek, Italian, Portuguese, Spanish and Swedish languages, each text being equally authentic.

Done at…

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ANNEXES
ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT

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1. Machinery
2. Electrical Safety
3. Electromagnetic Compatibility
4. Hot water Boilers
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8. Good Manufacturing Practice (GMP) for medicinal products for human use: inspection and batch certification

ANNEX ON MUTUAL RECOGNITION OF RESULTS OFCONFORMITY ASSESSMENT:

MACHINERY

SECTION I
COMMUNITY AND NATIONAL LAW

Community law: European Parliament and Council Directive 98/37/EC of 22 June 1998 on the approximation of the laws of the Member States relating to machinery (OJ L 207, 23.07.1998, p.1), as amended by European Parliament and Council Directive 98/79/EC of 27 October 1998 (OJ L 331, 07.12.1998, p.1).

Hungarian national law: Decree 21/1998. (IV.17.) IKIM of the Minister of Industry, Trade and Tourism on the safety requirements of machinery and assessment of their conformity (Magyar Közlöny 32, 17.04.1998, p. 2606) as last amended by Decree 60/1999. (XII.1.) GM (Magyar Közlöny 107, 01.12.1999, p. 6897).

Decree 4/1999. (II.24.) GM of MEA on the detailed rules on the designation of testing, inspection and certification bodies for conformity assessment of technical products (Magyar Közlöny 14, 24.02.1999, p. 1036).

SECTION II
NOTIFYING AUTHORITIES

European Community:

- Austria: Bundesministerium für wirtschaftliche Angelegenheiten.
- Belgium: Ministère des Affaires Economiques.
  Ministerie van Economische Zaken.
- Denmark: Direktoratet for Arbejdstilsynet.
- Finland: Sosiaali-ja terveysministeriö/Social-och hälsovårdsministeriet.
- France: Ministère de l'emploi et de la solidarité.Direction des relations du travail, Bureau CT 5.

  Ministère de l'économie, des finances et de l' industrie. Secrétariat d'Etat à l'industrie. Direction générale de l'industrie, des technologies de l'information et des postes (DiGITIP) - SQUALPI.
- Germany: Bundesministerium für Arbeit und Sozialordnung.

- Greece: Ministry of Development. General Secretariat of Industry.
- Ireland: Department of Enterprise and Employment.
- Italy: Ministero dell'Industria, del Commercio e dell'Artiginiato.
- Luxembourg: Ministère du Travail (Inspection du travail et des Mines).
- Netherlands: Minister van Sociale Zaken en Werkgelegenheid.
- Portugal: Under the authority of the Government of Portugal: Instituto Português da Qualidad.
- Spain: Ministerio de Industria y Energía.
- Sweden: Under the authority of the Government of Sweden:
  Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
- United Kingdom: Department of Trade and Industry.

Hungary: Gazdasági Minisztérium (Ministry of Economic Affairs - MEA)

SECTION III
NOTIFIED BODIES

European Community: Bodies which have been notified by the Member States of the European Community in accordance with the Community law of Section I and notified to Hungary in accordance with Article 10 of this Protocol.

Hungary: Bodies which have been designated by Hungary in accordance with the Hungarian national law of Section I and notified to the European Community in accordance with Article 10 of this Protocol.

SECTION IV
SPECIFIC ARRANGEMENTS

Safeguard Clauses

A. Safeguard clause relating to industrial products

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to the present annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of its investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards.

1. Where Hungary considers that a harmonised standard referred to in the legislation defined in the present annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the European Community to proceed in accordance with the procedure provided for in the Community legislation identified in the present annex.

3. The European Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT:

ELECTRICAL SAFETY

SECTION I
COMMUNITY AND NATIONAL LAW

Community law:	Council Directive 73/23/EEC of 19 February 1973 on the approximation of the laws of the Member States relating to electrical equipment designed for use within certain voltage limits (OJ L 77, 26.03.1973, p. 29), as last amended by Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.08.1993, p.1).
Hungarian national law:	Decree 79/1997. (XII.31.) IKIM of the Minister of Industry, Trade and Tourism on safety requirements of certain electrical equipment and assessment of conformity with those requirements (Magyar Közlöny 122 , 31.12.1997, p. 10100). Decree 4/1999. (II.24.) GM of MEA on the detailed rules on the designation of testing, inspection and certification bodies for conformity assessment of technical products (Magyar Közlöny 14, 24.02.1999, p. 1036).

SECTION II
NOTIFYING AUTHORITIES

• Austria:	Bundesministerium für wirtschaftliche Angelegenheiten.
• Belgium:	Ministère des Affaires Economiques. -Ministerie van Economische Zaken.
• Denmark:	Boligministeriet.
• Finland:	Kauppa ja teollisuusministeriö/Handels och industriministeriet.
• France:	Ministère de l'économie, des finances et de l'industrie. Secrétariat d'Etat à l'industrie. Direction générale de l'industrie, des technologies de l'information et des postes (DiGITIP) - SQUALPI.
• Germany:	Bundesministerium für Arbeit und Sozialordung
• Greece:	Ministry of Development. General Secretariat of Industry.
• Ireland:	Department of Enterprise and Employment.

• Italy:	Ministero dell' Industria, del Commercio e dell' Artigianato.
• Luxembourg:	Ministère de l'Economie- Service de l'Energie de l'Etat. Ministère du Travail (Inspection du Travail et des Mines).
• Netherlands:	Minister van Volksgezondheid, Welzijn en Sport (consumer goods). Minister van Sociale Zaken en Werkgelegenheid (others).
• Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
• Spain:	Ministerio de Industria y Energía
• Sweden:	Under the authority of the Government of Sweden : Styrelsen för ackreditering och teknisk kontrol (SWEDAC).
• United Kingdom:	Department of Trade and Industry
Hungary:	Gazdasági Minisztérium (Ministry of Economic Affairs- MEA)

SECTION III
NOTIFIED BODIES

European Community:	Bodies which have been notified by the Member States of the European Community in accordance with the Community law of Section I and notified to Hungary in accordance with Article 10 of this Protocol.
Hungary:	Bodies which have been designated by Hungary in accordance with the Hungarian national law of Section I and notified to the European Community in accordance with Article 10 of this Protocol.

SECTION IV
SPECIFIC ARRANGEMENTS

Safeguard Clauses

A. Safeguard clause relating to industrial products

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to the present annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards.

1. Where Hungary considers that a harmonised standard referred to in the legislation defined in the present annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the European Community to proceed in accordance with the procedure provided for in the Community legislation identified in the present annex.

3. The European Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITIONOf RESULTS OFCONFORMITY ASSESSMENT:

ELECTROMAGNETIC COMPATIBILITY

SECTION I
COMMUNITY AND NATIONAL LAW

Community law:	Council Directive 89/336/EEC of 3 May 1989 on the approximation of the laws of the Member States relating to electromagnetic compatibility (OJ L 139, 23.05.1989, p. 19), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.08.1993, p.1).
Hungarian national law:	Joint Decree 31/1999. (VI. 11.) GM-KHVM of the Ministers of Economic Affairs and Transport, Telecommunication and Water Management on electromagnetic compatibility (Magyar Közlöny 51,11.06. 1999, p. 3302), as amended by Joint Decree 58/1999. (X.27) GM-KHVM (Magyar Közlöny 93, 27.10.1999, p. 5840). Decree 4/1999. (II.24) GM of MEA on the detailed rules on the designation of testing, inspection and certification bodies for conformity assessment of technical products (Magyar Közlöny 14, 24.02.1999, p. 1036). Decree 22/1999. (VIII.4) KHVM of MTCWM on the detailed rules on the designation of testing, inspection and certification bodies for conformity assessment of certain telecommunication and information technology products (Magyar Közlöny 69, 04.08.1999, p. 4466).

SECTION II
NOTIFYING AUTHORITIES

European Community:

• Austria:	Bundesministerium für wirtschaftliche Angelegenheiten.
• Belgium:	Ministère des Affaires Economiques. Ministerie van Economische Zaken.
• Denmark:	Telestyrelsen.
• Finland:	Kauppa-ja teollisuusministeriö/Handels-och industriministeriet. For EMC aspects of telecommunications and radio equipment:Liikenneministeriö/Trafikministeriet.

• France:	Ministère de l'économie, des finances et de l'industrie. Secrétariat d'Etat à l'industrie. Direction générale de l'industrie, des technologies de l'information et des postes (DiGITIP) - SQUALPI.
• Germany:	Bundesministerium für Wirtschaft und Technologie.
• Greece:	Ministry of Development. General Secretariat of Industry.
• Ireland:	Department of Enterprise and Employment.
• Italy:	Ministero dell' Industria, del Commercio e dell' Artigianato.
• Luxembourg:	Ministère de l'Economie- Service de l'Energie de l'Etat.
• Netherlands:	Minister van Verkeer en Waterstaat.
• Portugal:	Under the authority of the Government of Portugal: Instituto Português da Qualidade.
• Spain:	Ministerio de Industria y Energía. For EMC aspects of telecommunications and radio equipment: Ministerio de Fomento.
• Sweden:	Under the authority of the Government of Sweden : Styrelsen för ackreditering och teknisk kontrol (SWEDAC).
• United Kingdom:	Department of Trade and Industry.
Hungary:	Gazdasági Minisztérium (Ministry of Economic Affairs - MEA) Közlekedési, Hírközlési és Vízügyi Minisztérium (Ministry of Transport, Communication and Water Management - MTCWM)

SECTION III
NOTIFIED AND COMPETENT BODIES

European Community:	Bodies which have been notified by the Member States of the European Community in accordance with the Community law of Section I and notified to Hungary in accordance with Article 10 of this Protocol.
Hungary:	Bodies which have been designated by Hungary in accordance with the Hungarian national law of Section I and notified to the European Community in accordance with Article 10 of this Protocol.

SECTION IV
SPECIFIC ARRANGEMENTS

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A. Safeguard clause relating to industrial products

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to the present annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards.

1. Where Hungary considers that a harmonised standard referred to in the legislation defined in the present annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the European Community to proceed in accordance with the procedure provided for in the Community legislation identified in the present annex.

3. The European Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT:

HOT WATERBOILERS

SECTION I
COMMUNITY AND NATIONAL LAW

Community law:	Council Directive 92/42/EEC of 21 May 1992 on efficiency requirements for new hot-water boilers fired with liquid or gaseous fuels (OJ No L 167, 22.06.1992 p.17), as amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.08.1993, p.1).
Hungarian national law:	Decree 20/1998. (IV.17.) IKIM of the Minister of Industry, Trade and Tourism on efficiency requirements for hot water boilers fired with liquid or gaseous fuels and assessment of their conformity (Magyar Közlöny 32, 17.04.1998, p. 2603. Decree 4/1999. (II.24.) GM of MEA on the detailed rules on the designation of testing, inspection and certification bodies for conformity assessment of technical products (Magyar Közlöny 14, 24.02.1999, p. 1036).

SECTION II
NOTIFYING AUTHORITIES

European Community

• Austria	Bundesministerium für wirtschaftliche Angelegenheiten.
• Belgium	Ministère des Affaires Economiques. Ministerie van Economische Zaken.
• Denmark	Boligministeriet.
• Finland	Ympäristöministeriö/Miljöministeriet.
• France	Ministère de l'économie, des finances et de l'industrie.Secrétariat d'Etat à l'industrie. Direction de l'action régionale et de la petite et moyenne industrie (DARPMI). Sous-direction de la sécurité industrielle. Direction générale de l'industrie, des technologies de l'information et des postes (DiGITIP) - SQUALPI.
• Germany	Bundesministerium für Wirtschaft und Technologie.

• Greece	Ministry of Development. General Secretary of Industry.
• Ireland	Department of Enterprise and Employment.
• Italy	Ministero dell'Industria, del Commercio e dell'Artiginiato.
• Luxembourg	Ministère de l'Environnement.
• Netherlands	Ministerie van Economische Zaken.
• Portugal	Ministério da Economia. InstitutoPortuguês da Qualidade.
• Spain	Ministerio de Industria y Energia.
• Sweden	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
• United Kingdom	Department of the Environment, Transport and the Regions.
Hungary:	Gazdasági Minisztérium (Ministry of Economic Affairs - MEA)

SECTION III
NOTIFIED BODIES

European Community:	Bodies which have been notified by the Member States of the European Community in accordance with the Community law of Section I and notified to Hungary in accordance with Article 10 of this Protocol.
Hungary:	Bodies which have been designated by Hungary in accordance with the Hungarian national law of Section I and notified to the European Community in accordance with Article 10 of this Protocol.

SECTION IV
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Safeguard Clauses

A. Safeguard clause relating to industrial products

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to the present annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards.

1. Where Hungary considers that a harmonised standard referred to in the legislation defined in the present annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the European Community to proceed in accordance with the procedure provided for in the Community legislation identified in the present annex.

3. The European Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT:

GAS APPLIANCES

SECTION I
COMMUNITY ANDNATIONAL LAW

Community law:	Council Directive 90/396/EEC of 29 June 1990 on the approximation of the laws of the Member States relating to appliances burning gaseous fuels(OJ L 196, 26.07.1990, p. 15) , as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ No L 220, 30.08.1993, p. 1)
Hungarian national law:	Decree 22/1998. (IV.17.) IKIM of the Minister of Industry, Trade and Tourism on the design of certain appliances burning gaseous fuels and the assessment of their conformity (Magyar Közlöny 32, 17.04.1998, p. 2629), as last amended Decree 67/1999. (XII.15.) GM (Magyar Közlöny 113, 15.12.1999, p. 7506). Decree 4/1999.(II.24.) GM of MEA on the detailed rules on the designation of testing, inspection and certification bodies for conformity assessment of technical products (Magyar Közlöny 14, 24.02.1999, p. 1036).

SECTION II
NOTIFYING AUTHORITIES

European Community

• Austria	Bundesministerium für wirtschaftliche Angelegenheiten.
• Belgium	Ministère des Affaires Economiques. Ministerie van Economische Zaken.
• Denmark	Danmarks Gasmaterial Prøvning.
• Finland	Kauppa-ja teollisuusministeriö/Handels-och industriministeriet.
• France	Ministère de l'économie, des finances et de l'industrie. Secrétariat d'Etat à l'industrie. Direction de l'action régionale et de la petite et moyenne industrie (DARPMI). Sous-direction de la sécurité industrielle. Direction générale de l'industrie, des technologies de l'information et des postes (DiGITIP) - SQUALPI
• Germany	Bundesministerium für Arbeit und Sozialordnung

- Greece — Ministry of Development. General Secretary of Industry.
- Ireland — Department of Enterprise and Employment.
- Italy — Ministero dell'Industria, del Commercio e dell'Artiginiato.
- Luxembourg — Ministère du Travail (Inspection du Travail et des Mines).
- Netherlands — Ministerie van Economische Zaken.
- Portugal — Ministério da Economia. InstitutoPortuguês da Qualidade.
- Spain — Ministerio de Industria y Energía.
- Sweden — Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC)
- United Kingdom — Department of Trade and Industry.

Hungary: Gazdasági Minisztérium (Ministry of Economic Affairs -MEA)

SECTION III
NOTIFIED BODIES

European Community:

Bodies which have been notified by the Member States of the European Community in accordance with the Community law of Section I and notified to Hungary in accordance with Article 10 of this Protocol.

Hungary:

Bodies which have been designated by Hungary in accordance with the Hungarian national law of Section I and notified to the European Community in accordance with Article 10 of this Protocol.

SECTION IV
SPECIFIC ARRANGEMENTS

Safeguard Clauses

A. Safeguard clause relating to industrial products

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to the present annex, it shall immediately inform the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge, and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards.

1. Where Hungary considers that a harmonised standard referred to in the legislation defined in the present annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the European Community to proceed in accordance with the procedure provided for in the Community legislation identified in the present annex.

3. The European Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT:

MEDICAL DEVICES

SECTION I
COMMUNITY AND NATIONAL LAW

Community law:	Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.07.1990, p. 17), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.08.1993, p. 1) Council Directive 93/42/EEC of 14 June 1993 concerning medical (OJ L 169, 12.07.1993, p. 1), as last amended by European Parliament and Council Directive 98/79/EC of 27 October 1998 (OJ L 331, 07.12.1998, p.1).
Hungarian national law:	Decree 47/1999. (X.6.) EüM of the Ministry of Health on medical devices (Magyar Közlöny 88, 06.10 1999, p. 5512). Decree 48/1999 (X.6) EüM of MH on the detailed rules on the designation of testing, inspection and certification bodies for conformity assessment of medical devices (Magyar Közlöny 88, 06.10.1999, p. 5544).

SECTION II
NOTIFYING AUTHORITIES

European Community:

• Austria:	Bundesministerium für Arbeit, Gesundheit und Soziales
• Belgium:	Ministère de la Santé Publique, de l'Environment et de l'IntegrationSociale. Inspection Pharmaceutique. /Ministerie van Volksgenzondheid, Leefmilieu en Sociale Integratie. Farmaceutische Inspectie. Ministère des Affaires Economiques/Ministerie van Economische Zaken.
• Denmark:	Sundhedsministeriet.
• Finland:	Sosiaali-ja terveysministeriö/Social-och hälsovårdsministeriet

• France:	Ministère de l'emploi et de la solidarité. Direction générale de la santé. Ministère de l'économie, des finances et de l'industrie.Secrétariat d'Etat à l'industrie.Direction générale de l'industrie, des technologies de l'information et des postes (DiGITIP) - SQUALPI.
• Germany:	Bundesministerium für Gesundheit.
• Greece:	Ministry of Health.
• Ireland:	Department of Health.
• Italy:	Ministero della Sanità.
• Luxembourg:	Ministère de la Santé.
• Netherlands:	Ministerie van Volksgezondheid, Welzijn en Sport; inspectie Volksgezondheid.
• Portugal:	Ministerio da Saude.
• Spain:	Ministerio Sanidad y Consumo.
• Sweden:	Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC).
• United Kingdom:	Department of Health.
Hungary:	Egészségügyi Minisztérium (Ministry of Health – MH)

SECTION III
NOTIFIED BODIES

European Community:	Bodies which have been notified by the Member States of the European Community in accordance with the Community law of Section I and notified to Hungary in accordance with Article 10 of this Protocol.
Hungary:	Bodies which have been designated by Hungary in accordance with the Hungarian national law of Section I and notified to the European Community in accordance with Article 10 of this Protocol.

SECTION IV
SPECIFIC ARRANGEMENTS

1. Registration of the person responsible for placing devices on the market

Any manufacturer who places on the market of one of the Parties the medical devices referred to in Article 14 of Directive 93/42/EEC and in the relevant Hungarian national law shall inform the competent authorities of the Party in which he has his registered place of business of the particulars referred to in these provisions. The Parties shall reciprocally recognise that registration. The manufacturer shall not be obliged to designate a person responsible for placing devices on the market established in the territory of the other Party.

2. Labelling of medical devices

Manufacturers of both Parties shall indicate their name or trade name and address on the label of medical devices as specified in Annex 1, point 13.3(a) to Directive 93/42/EEC and in the relevant Hungarian national law. They shall not be obliged to indicate the name and address of the person responsible for placing the device on the market, of the representative or of the importer established within the territory of the other Party on the label, outer packaging or instructions for use.

3. Information exchanges

In accordance with Article 12 of the Protocol, the Parties shall in particular exchange the information referred to in the relevant Community law and Hungarian national law, in particular:

- data relating to registration of manufacturers and devices;
- data relating to certificates issued, modified, supplemented, suspended, withdrawn or refused;
- data obtained in accordance with the vigilance procedure.

4. Safeguard clause

A. Safeguard clause relating to industrial products in products.;

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to the present annex, it shall immediately inform to the other Party, indicating the reasons for its decision and how non compliance has been assessed.

2. The Parties shall consider the matter and the evidence brought to their knowledge and shall report to each other the results of their investigations.

3. In case of agreement, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

4. In case of disagreement on the outcome of such investigations the matter shall be forwarded to the Association Council who may decide to have an expertise carried out.

5. Where the Association Council finds that the measure is:

   a) unjustified, the national authority of the Party who has taken the measure shall withdraw it;

   b) justified, the Parties shall take appropriate measures to ensure that such products are not placed on the market.

B. Safeguard clause relating to harmonised standards.

1. Where Hungary considers that a harmonised standard referred to in the legislation defined in the present annex, does not meet the essential requirements of such legislation, it shall inform the Association Council giving the reasons thereof.

2. The Association Council shall consider the matter and may request the European Community to proceed in accordance with the procedure provided for in the Community legislation identified in the present annex.

3. The European Community shall keep the Association Council and the other Party informed of the proceedings.

4. The outcome of the procedure shall be notified to the other Party.

ANNEX ON MUTUAL RECOGNITIONOF RESULTS OF CONFORMITY ASSESSMENT:

GOODLABORATORY PRACTICEFOR MEDICINALPRODUCTS FOR HUMAN USE

SECTION I

COMMUNITY AND NATIONAL LAW

Community law:

Good Laboratory Practice:

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(OJ N° L 15, 17.01.87, p. 29) as last amended by Commission Directive 1999/11/EC of 8 March 1999 (OJ L 77, 23.03.99, p. 8).

Monitoring of Good Laboratory Practice

Council Directive 88/320/EEC of 9 June 1988 on the inspection and verification of Good Laboratory Practice (GLP) (OJ L 145, 11.06.88, p. 35) , as last amended by Commission Directive1999/12/EC of of 8 March 1999 (OJ L 77, 23.03.99, p. 22)

Medicinal Products :

Council Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products(OJ N° L 15, 17.01.87, p. 36).

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 (OJ N° L 15, 17.01.87, p. 31). 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 Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of propietary medicinal products(OJ N°L 270, 26.09.91, p. 32)

Hungarian national law:

Good Laboratory Practice and Monitoring of Good Laboratory Practice:

Joint Decree 31/1999 (VIII.6.) EüM - FVM of the Minister of Health and the Minister of Agriculture and Rural Development on the application and monitoring of good laboratory practice relating to human medicines and pesticides (Magyar Közlöny 70, 06.08.1999, p. 4521).

Medicinal Products:
Act XXV of 1998 on medicines for human use (Magyar Közlöny 28, 01.04.1998, p. 2385).

SECTION II
NOTIFIED TEST FACILITIES

For the purpose of this Sectoral Annex, the term "Notified Test facilities" means the test facilities recognised under each Party's GLP monitoring programme.

Each Party shall provide the other Party at least annually with a list of the test facilities which, in the light of the results of the inspections and study audits conform to the GLP principles as well as of the dates of inspection or study audit, their GLP compliance status, and the area of expertise in accordance with point 4 of the Appendix to Annex III of the OECD Decision-Recommendation of 2 October 1989 C(89)87(Final).

Each Party shall notify without delay the other Party when a listed test facility under its jurisdiction fails to conform to the GLP principles to an extent which may jeopardise the integrity or authenticity of any such studies it conducts. The test facility will be deleted from the list established in accordance with the preceding paragraph.

SECTION III
NOTIFYING AUTHORITIES

For the purpose of this Sectoral Annex, the term "Notifying Authorities" means the GLP Monitoring Authorities of the Parties.

European Community

- **Austria** — Bundesministerium für Umwelt, Jugend und Familie.
- **Belgium** — Ministère de la Santé Publique. Institut Scientifique pour la Santé Publique - Louis Pasteur. Ministerie van Volksgezondheid. Wetenschappelijk Instituut voor Volksgezondheid.– Louis Pasteur.
- **Denmark** — Lægemiddelstyrelsen (Danish Medicines Agency).
- **Finland** — Sosiaali- ja terveysministeriö/Social- och hälsovårdsministeriet
- **France** — Ministère de l'emploi et de la solidarité. Direction générale de la santé. Agence française de sécurité sanitaire des produits de santé (AFSSAPS). Ministère de l'économie, des finances et de l'industrie. Secrétariat d'Etat à l'industrie.Direction générale de l'industrie, des technologies de l'information et des postes

(DiGITIP).

- **Germany** Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit
- **Greece** General Chemical State Laboratory.
- **Ireland** Irish Laboratory Accreditation Board (ILAB)
- **Italy** Ministry of Health. Department of Prevention. GLP Compliance Monitoring Unit.
- **Netherlands** Ministerie van Volksgezondheid, Welzijn en Sport;

  inspectie Volksgezondheid.
- **Portugal** Instituto National de Farmacia e do Medicamento(INFARMED).
- **Spain** Agencia Española del Medicamento.
- **Sweden** Läkemedelsverket (Medical Products Agency).
- **United Kingdom** Department of Health. GLP Monitoring Authority.

Hungary: Országos Gyógyszerészeti Intézet - OGYI (National Institute of Pharmacy)

SECTION IV
SPECIFIC ARRANGEMENTS

The provisions of this Sectoral Annex apply to the non-clinical testing of medicinal products according to Good Laboratory Practice (GLP), being either substances or preparations, covered by the legislative, regulatory and administrative requirements listed in section I.

Unless specific definitions are given, the definition of terms in the OECD Principles of Good Laboratory Practice as contained in Annex II to 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 to 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, shall apply.

The Parties recognise the equivalence of each other's GLP compliance programmes that are in accordance with the legislative, regulatory, and administrative requirements listed in Section I, which are consistent with the OECD Decision-Recommendation of 2 October 1989 C(89)87(Final),The Parties mutually accept the conclusions of study audits and test facility inspections on the GLP compliance status performed by the competent authorities referred to in section III.

Test facility inspections and/or study audits shall be carried out in accordance with the legislative, regulatory, and administrative requirements of the Party under the jurisdiction of which the studies and data generated therefrom are produced.

Each Party recognises studies and data generated therefrom produced by a test facility of the other Party as studies and data generated therefrom produced by the test facilities complying with the GLP principles under its own jurisdiction, provided that the test facility is included in the list established in accordance with Section II.

The provisions of this sectoral Annex shall enter into operation upon decision of the Association Council. This decision will be taken in the light of the Mutual Joint Visits (MJV) carried out in Hungary according to the OECD Pilot Project on Examination of National GLP Compliance Monitoring Programmes.

Procedure for application of the safeguard clause

1. Each Party may request further test facility inspections or study audits if there is a documented doubt as to whether a study was conducted in accordance with GLP.

2. The Party from which the data are originating shall consider the matter and the evidence brought to its knowledge. It shall report to the other Party the results of its investigations.

3. In case of agreement, the Party from which the data are originating shall take appropriate measures to rectify the situation of the test facility.

4. If, in exceptional cases, doubts persist and the requesting Party can justify a special concern, it may, designate one or more experts of its authorities listed in section III to participate in a laboratory inspection or an audit of a study conducted jointly by the authorities of the Parties upon decision of the Association Council.

Co-operation

Each Party may, on request, participate as an observer in an inspection of a test facility conducted by the competent authorities of the other Party with the consent of the test facility concerned in order to maintain a continuing understanding of the other Party's inspection procedures.

The Parties shall supply each other with additional information on a test facility inspection or study audit in response to a reasonable request from the other Party.

ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY ASSESSMENT:

GOOD MANUFACTURINGPRACTICE FOR MEDICINAL PRODUCTS FOR HUMANUSE : INSPECTION AND BATCH CERTIFICATION

SECTION I

COMMUNITY AND NATIONAL LAW

Community law:	Council Directive 65/65/EEC, of 26 January 1965 on the approximation of provisions laid down by law, regulation or administrative action relating to medicinal products (OJ L 22, 09.02.1965, p.369), as last amended by Council Directive 93/39/EEC of 14 June 1993 (OJ L 214, 24.08.1993, p.22).
	Council Directive 75/318/EEC, of 20 May 1975 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 medicinal products (OJ L 147, 09.06.1975, p.1), as last amended by Commission Directives 1999/82/EC and 1999/83/EC of 8 September 1999 (OJ L 243, 15.09.1999, p. 7 and 9).
	Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation on administrative action relating to medicinal products (OJ L 147, 09.06.1975, p. 13), as last amended by Council Directive 93/39/EEC of 14 June 1993 (OJ L 214, 24.08.1993, p. 22).
	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 (OJ L 193, 17.07.1991, p.30).
	Council Regulation (EEC) N° 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 (OJ L 214, 24.08.1993, p.1) as last amended by Commission Regulation (EC) N° 649/98 of 23 March 1998 (OJ L 88, 24.03.1998, p. 7).
	Council Directive 92/25/EEC, of 31 March 1992 on the wholesale distribution of medicinal products for human use (OJ L 113, 30.04.1992, p.1) & Guide to Good Distribution Practice.
	Guide to Good Manufacturing Practice, Volume IV of the Rules Governing Medicinal Products in the European Community.
Hungarian national law:	Decree 37/2000 .(III.23.) Korm. of the Government on the subjective and objective requirements of manufacture of medicines for human use (Magyar Közlöny 25, 23.03.2000, p.1206).
	Act XXV of 1998 on medicines for human use (Magyar

Közlöny 28,01.04.1998, p. 2385).

Law Decree 31/1976, which is based on the proclamation of the international treaty came into force on 9-11 October 1970 in Geneva, dealing with the subject of mutual acknowledgement of supervision during the manufacturing of pharmaceutical products.(Magyar Közlöny 94, 11.12.1976, p.1139).

Decree 13/1987 EüM (VIII.19) of the Minister of Health on the registration and placing on the market of pharmaceutical products (Magyar Közlöny 36, 19.08.1987, p. 698).

SECTION II
OFFICIAL GMP INSPECTION SERVICES OF EACH PARTY

European Community

• Austria	Bundesministerium für Arbeit, Gesundheit und Soziales.
• Belgium	Ministère de la Santé Publique, de l'Environment et de l'Intégration Sociale. Inspection Pharmaceutique. Ministerie van Volksgenzondheid, Leefmilieu en Sociale Integratie. Farmaceutische Inspectie.
• Denmark	Lægemiddelstyrelsen (Danish Medicines Agency).
• Finland	Sosiaali-ja terveyministeriö/Social-och hälsovardsministeriet.
• France	Ministère de l'emploi et de la solidarité. Direction générale de la santé. Agence française de sécurité sanitaire des produits de santé.
• Germany	Bundesministerium für Gesundheit.
• Greece	Ministry of Health and Welfare, National Drug Organization (E.O.F.).
• Ireland	Irish Medicines Board.
• Italy	Ministero della Sanità. Dipartimento Farmaci e Farmacovigilanza.
• Luxembourg	Direction de la Santé, Division de la Pharmacie et des Médicamen
• Netherlands	Ministerie van Volksgezondheid, Welzijn en Sport; inspectie Volksgezondheid.
• Portugal	Instituto da Farmácia e do Medicamento (INFARMED).
• Spain	Agencia Española del Medicamento.
• Sweden	Läkemedelsverket (Medical Products Agency).

- United Kingdom Medicines Control Agency.

Hungary: Országos Gyógyszerészeti Intézet - OGYI (National Institute of Pharmacy).

SECTION III
SPECIFIC ARRANGEMENTS

1. Definitions

"Medicinal products" means all products regulated by the pharmaceutical legislation in the European Community and Hungary as listed in Section I above.

"Good Manufacturing Practice (GMP)": as defined in Council Directive 91/356/EEC and the relevant legislation of Hungary as listed in Section I above.*"Inspection":* means an on-site evaluation of a manufacturing facility carried out by an inspection service listed in section II above to determine whether such manufacturing facility is operating in compliance with Good Manufacturing Practice or commitments made as part of the marketing authorisation.

"Inspection Report": means the written observations and Good Manufacturing Practice compliance assessment completed by an authority listed in Section II above.

2. Scope and Coverage

2.1 The provisions of this Sectoral Annex cover all medicinal products for human use which are industrially manufactured in Hungary and the European Community, and to which the European Community and Hungarian GMP requirements apply.

2.2 For the medicinal products covered by this Sectoral Annex, each Party shall recognise the conclusions of inspections carried out by the relevant inspection services of the other Party and the relevant manufacturing authorisations granted by the Competent Authorities of the other Party.

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

3. Pre-Operational phase

3.1 In the pre-operational phase the following activities will be carried out:

- The effective implementation of legislative, regulatory and administrative requirements of the European Community on GMP by Hungary will be determined according to a procedure established by the European Community.

- The practical implementation of the requirements of the European Community on GMP will be determined through joint inspections, examination of inspection reports and other documents linked to an inspection.

3.2 The length of the pre-operational phase will be 6 month.

3.3 The results of the activities in the pre-operational phase will be discussed in the competent expert group (European Community inspector's Working Party) with the

participation of the competent authorities of Hungary.The Parties will decide on the prolongation or termination of the pre-operational phase in the Association Council. The operational phase will start immediately after the successful termination of the pre-operational phase.

3.4 The Parties may decide, in the Association Council, to renounce the pre-operational phase at any time in the light of the demonstration of implementation and maintenance of Good Manufacturing Practice in Hungary.

4.Operational phase

Certification of manufacturers

4.1 At the request of an exporter, importer or the Competent Authority of the other party, the authorities responsible for granting manufacturing authorisations and for supervision of the manufacture and control of medicinal products shall certify that the manufacturer of the medicinal product:

a) is appropriately authorised to manufacture and/or control the relevant medicinal product or to carry out the relevant specified operations;

b) complies with the European Community and Hungarian GMP requirements; and,

c) is regularly inspected by the competent inspection service.

4.2 The certificates shall also identify the site(s) of manufacture. Guidance on a common format for such certificate will be given**.**

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

Batch certification

4.4 Each batch exported shall be accompanied by a batch certificate issued by the manufacturer (self certification) after a full qualitative analysis, a quantitative analysis of all the active constituents and all the other tests or checks necessary to ensure the quality of the product in accordance with the requirements of the marketing authorisation. This certificate shall attest that the batch meets its specification and has been manufactured in accordance with the relevant marketing authorisation. This certificate shall be retained by the importer of the batch and will be made available upon request of the Competent Authority.

4.5 When issuing a certificate, the manufacturer shall take account of the provisions of the current European Community certification. The batch certificate shall be signed by the person responsible for releasing the batch for export, i.e. the "qualified person" referred to in Article 17 of Directive 75/319/EEC and in Article 24(2) i) of Act XXV of 1998 on medicines for human use.

Official batch release

4.6 The official batch release procedure is an additional verification of safety and efficacy of immunological medicinal products (e.g. vaccines) and blood derivatives, carried out by the

competent authorities before the distribution of each batch of product. This Protocol does not encompass mutual recognition of these official batch releases.

Inspections

4.7 GMP inspections shall be carried out by the locally competent inspection service against the GMP requirements as listed in Section I.

4.8 The following types of inspections may be carried out:

a) General or system inspections: carried out to verify whether a manufacturer complies generally with GMP requirements (e.g. routine inspection covering especially the fundamental requirements of GMP).

b) Process inspections: carried out to verify whether a manufacturer conducts a certain process (es) according to GMP requirements (e.g. production of sterile water).

c) Product inspection: carried out to verify whether a manufacturer produces certain medicinal product or a series of product(s) according to GMP requirements. It focuses on the validation of compliance with specific process or control aspects as described in the marketing authorisation (e.g. "pre-marketing" inspections) and therefore the inspector shall have available and be conversant with the relevant information (the quality dossier and an application/authorisation dossier).

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

Transmission of inspection reports

4.10 Upon reasoned request, the relevant inspection services shall forward a copy of the last inspection report of the manufacturing or control site, in case analytical operations are contracted out. Each Party shall deal with these inspection reports with the degree of confidentiality requested by the Party of origin.

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

Alert system

4.12 The Competent Authorities will inform the authorities of the other Party with the appropriate speed in case of quality defect, batch recalls, counterfeiting and other problems concerning quality, which could necessitate additional controls or suspension of the distribution of the batch. A detailed alert procedure shall be agreed between the Parties.

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

Exchange of information between authorities and approximation of quality requirements

4.14 In accordance with the general provisions of this Protocol, the Parties shall exchange any information necessary for the mutual recognition of inspections.

4.15 In addition, the Competent Authorities shall keep each other informed of any new technical guidance or inspection procedure. Each Party shall consult the other before their adoption and will endeavour to proceed towards their approximation.

Inspectors training

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

Joint inspections

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

Contact points

4.18 For the purpose of this Protocol, the contact points for the alert system, any technical question, such as exchange of inspection reports, inspectors training sessions, technical requirements are,

for the European Community:

the Director of the European Agency for the Evaluation of Medicinal Products

for Hungary:

Országos Gyógyszerészeti Intézet, főigazgató (National Institute of Pharmacy, Director General).

Divergence of views

4.19 Both Parties shall use their best endeavours to resolve any divergence of views concerning *inter alia* compliance of manufacturers and conclusions of inspection reports. Unresolved divergences of view will be referred to the Association Council.

5. SAFEGUARD CLAUSES

5.1 Where a party establishes in writing and in an objective and reasoned manner that the other Party is failing to comply with the conditions of this Annex, it may consult the Association Council. The Association Coincil may decide on measures to be taken.

5.2 Each Party reserves the right to conduct its own inspection for reasons identified to the other Party. Such inspections are to be notified in advance to the other Party, which has the

option of joining the inspection. Recourse to this safeguard clause should be an exception. Should such an inspection take place, inspection costs may be recovered.

DECLARATION BY THE EUROPEAN COMMUNITY ON THE ATTENDANCE OF HUNGARIAN REPRESENTATIVES TO COMMITTEES

In order to ensure a better understanding of the practical aspects of the application of the acquis communautaire, the European Community declares that Hungary is invited, under the following conditions, to the meetings of the committees established or referred to under the Community law on machinery, electromagnetic compatibility, gas appliances, and medical devices.

This participation shall be limited to meetings or parts thereof during which the application of the acquis is discussed; it shall not entail attendance to meetings intended to prepare and issue opinions on implementing or management powers delegated to the Commission by the Council.

This invitation may be extended, on a case-by-case basis, to groups of experts convened by the European Commission.

FINANCIAL STATEMENT 2001-2005

External trade relations - Protocol to the Europe Agreement between the European Community and Hungary on Conformity Assessment and Acceptance of Industrial Products (PECA)

1. TITLE

External Trade Relations-

Protocol to the Europe Agreement between the European Communities and Hungary on Conformity Assessment and Acceptance of Industrial Products (PECA)

2. BUDGETARY HEADINGS: B7-8500

3. LEGAL BASIS

Article 133 of the Treaty establishing the European Community.

Proposal for a Council decision N°.... on the conclusion by the European Community of an additional Protocol to the Europe Agreement between the European Community and Hungary on Conformity Assessment and Acceptance of Industrial Products (PECA).

4. DESCRIPTION OF OPERATION:

4.1 General objective:

The main objective of the PECA is to facilitate trade by means of the elimination of technical barriers in respect of industrial products in certain sectors in which the candidate country has aligned its legislation on the acquis communautaire.

The purpose of this PECA is to establish the mutual acceptance of industrial products which fulfil the requirements to be lawfully placed on the market and the mutual recognition of the results of conformity assessment of industrial products subject to the Community technical regulations and to the equivalent Hungarian national legislation.

The major actions, which will be pursued by the Commission under this budget line, will be the following:

- Confidence-building activities to facilitate the proper implementation of the PECA.
- Management of the PECA and maintenance of the necessary degree of confidence.
- Extension of the PECA to new sectors.

The Commission will be assisted by experts, particularly in regard to sectoral activities. It will however remain the final arbiter in the management of this PECA.

4.2 Duration of the action; means foreseen for its renewal:

The general action undertaken will be of a definite duration. The PECA has a lifetime limited to the pre-accession period of Hungary. The initial period of confidence building will require a more intensive effort but the expenditure should be substantially less after 1 year. However,

during the life of the PECA a continued effort will be needed to ensure management and maintenance of confidence.

5. CLASSIFICATION OF EXPENDITURE/REVENUE

5.1 Non-compulsory expenditure ("DNO")

5.2 Differentiated appropriation ("CD")

5.3 Type of revenue involved:

None

6. TYPE OF EXPENDITURE/REVENUE

- *100% subsidy: No*

- *subsidy for co-financing with other sources in the public or private sector?*

Yes, this may be envisaged as a method of funding. Subsidies will be awarded according to the Commission's "Vademecum on grant management". Grant can be provided to professional associations and other responsible organisations for activities related to the implementation of the PECA.

- *Interest subsidy: No*

- *Others*

Financing of events, acquisition of studies, publications and conferences.

- *Should the action prove an economic success, is there provision for all, or part of, the Community contribution to be reimbursed?* Not relevant

- *Will the proposed operation cause any changes in the level of revenue?* No

7. FINANCIAL IMPACT ON APPROPRIATIONS FOR OPERATIONS

7.1 Method of calculating the total cost of the operation:

The estimation of costs is based on the anticipated requirements in terms of expenses related to seminars, workshops, travel of experts, verification of conformity assessment bodies, information and studies. The total estimated cost is based on the sum of the individual actions.

A range of different actions is foreseen to meet the objectives of the budget-line and costs will vary depending on the nature of action undertaken. Even for similar types of action (e.g. seminars) costs will vary depending on the scope of the action and the degree of specialisation needed.

The costs of specific actions will be determined either:

- by the Commission when it organises activities itself, e.g. seminars

- following invitations to tender issued by the Commission

- following requests for subsidies. In such cases, projects are selected according to how well they meet the criteria that have been established for selection. Subsidies will be awarded and managed according to the rules of the "Vademecum on grant management".

A. Attendance at the Association Council, the Association Committee or any special subcommittee or group to which has been delegated the management of the PECA.

This will be attended by Commission officials and some experts from the Member States. Travel and per diem expenses should be foreseen within the normal range of such expenses. The travel expenditure for officials will be covered by the "Mission budget" (A-7010). The reimbursement of travel and related expenses for experts will be made on line B7-8500.

B. Workshops and Seminars

These will be held to familiarise economic and other operators with the requirements of the PECA. The cost of these seminars will vary according to the subject matter and location, and will include travel and organisational costs (when in the EC) and substantial travel costs when in Hungary. Organisational costs will cost c. 3000 Euro each. The number of seminars will vary depending on the individual industrial sectors covered by the PECA.

C. Verification actions

The competence of the notified bodies will in some cases have to be checked, more so in the initial period of the PECA, but as a matter of course throughout the life of the PECA to maintain confidence in the system.

This will involve on-site assessment by teams of experts of notified bodies in the partner country in the initial stages, and subsequently investigation of complaints. This expenditure will cover all sectors of the PECA and may involve several notified bodies in each sector.

D. Production and dissemination of information

Certain costs may need to be incurred for the dissemination of information. Guides to regulations and assessment procedures may be needed typically at a cost of 10000 Euro.

7.2 Breakdown by elements of the operation

In Euro

(current prices)

Breakdown	Year 2001	Year 2002	2003	2004	2005	Total 2001-2005
A. Committee	11.128	11.128	11.128	11.128	11.128	55.640
C. Seminars	11.422	7.672				19.094
D. Verifications	8.928	8.928	4.464	4.464	4.464	31.248
E. Information	20.000	5.000	5.000			30.000
Total	51.478	32.728	20.592	15.592	15.592	135.982

From the year 2002 on the estimates are for information. The year number and the total amount will depend on the accession year of Hungary.

7.3 Indication of the timetable for commitment and payment appropriations

1000 Euro

	Year 2001	2002	2003	2004	2005	2005 and following years	Total
Schedule of Commitment	51	33	20	16	16	16	151
Payment appropriations							
2001	51						51
2002		33					33
2003			20				20
2004				16			16
2005					16		16
2006						16	16
Total	51	33	20	16	16	16	151

The year number and the total amount will depend on the accession year of Hungary.

8. WHAT ANTI-FRAUD MEASURES ARE PLANNED IN THE PROPOSAL FOR THE OPERATION?

Methods of control (submission of reports, etc.) will be included in all contracts or grant agreements between the Commission and beneficiaries.

A close co-operation with the delegations of the Commission and the participation of a representative of the Commission at events in third countries will check on the spot the work to ensure that it corresponds with the terms of reference, contract provisions and required professionalism.

The checks take place before the final payment. The same rule applies to the financial incentives paid to participating companies. Where appropriate, agreements also require organisations to submit financial accounts certified by their auditors.

9. ELEMENTS OF COST-EFFECTIVENESS ANALYSIS

9.1. Specific objectives of the proposed operation, population targeted

- *The specific objectives of Protocols on Conformity Assessment and Acceptance of Industrial Products are:*

- to avoid duplication of certification by economic operators.

- to promote exports, employment, competitivity and investment.

- to reduce costs, in particular for small and medium-sized enterprises and ultimately for the consumer,

- to extend certain benefits of the Internal Market to Hungary

- to ensure the effective operation of the Internal Market in certain sectors before accession of Hungary.

- *Target population*

The target population are the exporting companies, business associations, chambers of commerce and public institutions of the European Union and the general consumer which will benefit, or have an interest in, the mutual acceptance of industrial products and recognition of results of conformity assessment certification.

9.2. Reasons for the operation

- *Need for intervention from the Community budget*

Under Article 133 of the Treaty the Community has exclusive competence for commercial policy and this agreement have been negotiated in accordance with a mandate of the Council of Ministers and in consultation with the 133 Committee. The Commission will be responsible for implementation and management of this Protocol.

- *Choice of methods of intervention*

- *advantages over alternative measures (comparative advantages)*

- *analysis of similar operations at Community or national level*

- *results and expected multipliers*

The choice of management method (Association Council) has been set out in the PECA and constitute a minimum necessary for the proper functioning of the PECA. The use of seminars in the initial phases will allow ensuring familiarity with other systems.

These seminars and verifications are also designed to build mutual confidence; verifications will also be required to ensure this confidence is maintained throughout the life of the PECA. Confidence and its maintenance are keys to the successful operation of the PECA.

The importance of this budget is justified when put in perspective with the trade involved in this PECA and the yearly savings for EU exporters which are expected (estimated on a yearly basis at € 67 million for EU exporters to Hungary).

- *Main factors of uncertainty which could affect the specific results of the operation.*

* None

9.3 Monitoring and evaluation of the operation

- *Performance indicators selected*

** Output indicators*

** indicators of impact, following the objectives chosen*

In the case of this PECA, success can be quantified by trade facilitation through avoidance of duplication of testing and certification and costs. Yearly estimated savings for the European Community are indicated above (9.2).

Success can also be measured by increased EU exports and this factor will be taken into consideration although export performance is subject to such a wide range of variables (e.g. changes in exchange rates) that this can never be the sole factor for evaluation.

- *Evaluation of results*

Progress in the attainment of the PECA objectives will be monitored by Commission officials, the Association Council and by the economic operators concerned.

Details and frequency of the planned evaluation

The evaluation of the effectiveness and usefulness of the PECA will be regularly monitored by the Commission, by the Association Council at its annual meeting, by the Association Committee at its annual meeting, or by any special subcommittee or group to which the Association Council has delegated the management of the PECA. At least, the first major evaluation will be two years after the entry into force.

10. ADMINISTRATIVE EXPENSES

Human resources and administrative means are to be covered by the credits already allocated to the managing service. There is no request for additional staff.

10.1 Effect on the number of posts (considering that 8 industrial sectors are covered by the PECA).

Type of post		Staff to be assigned to managing the operation		Source		Duration
		Permanent posts DG I + sectoral DGs	Temporary posts	Existing resources in the DGs (DG Trade, Enlarge, Enter and Trend) or departments concerned	Additional resources	
Officials	A	1.2	None	1.2	None	Permanent
	B					
	C	0.4		0.4		
Other resources		None				
Total		1.6		1.6		

10.2 Overall financial impact of additional human resources: 1.6 staff (108.000 Euro per staff member per year = 172.800 Euro). (Headings A1, A2, A4, A5 and A7).

10.3 Increase in other administrative expenditure as a result of the operation (A-7010: missions)

The expenses set out below relate to travel expenses for officials of the Commission attending meetings of the Association Council, the Association Committee or any special subcommittee or group to which has been delegated the management of the PECA; seminars and verifications, when these are outside Brussels. These will be taken care of by the relevant budget allocations of various Directorates Generals involved.

For 2001 this involves the following calculation (the additional missions will be covered by the allocation on A-7010):

Budget heading	Amounts (Euro)	Method of calculation	
		No. of missions	Mission Unit cost
Committee A-7010	5.952	Hungary: 4	Brussels: Travel: 800 Euro; per diem: 150 Euro Hungary: Travel 1058 Euro; per diem: 215 Euro
Seminars A-7010	1.918	Hungary: 1	
Verifications A-7010	2.976	Hungary: 2	
A-7010: Total	10.846	7	

In Euro

	Year 2001	Year 2002	2003	2004	2005	Total 2001-2005
A. Committee	5.952	5.952	5.952	5.952	5.952	29.760
B. Seminars	1.918					1.918
C. Verifications	2.976	2.976	1.488	1.488	1.488	10.416
TOTAL	10.846	8.928	7.440	7.440	7.440	42.094

The above-mentioned figures are for information only. The impact on staff and missions will be covered by the allocations on the A-7 budget starting in the year 2001, and will depend on the accession date of Hungary.

IMPACT ASSESSMENT FORM

THE IMPACT OF THE PROPOSAL ON BUSINESS
with special reference to small and medium-sized enterprises

Title of proposal

Proposal for Council Decisions on the signature and on the conclusion of an additional Protocol to the Europe Agreement between the European Community and Hungary on Conformity Assessment and Acceptance of Industrial Products (PECA).

Reference number

The proposals

These decisions are necessary to conclude the Protocol to the Europe Agreement between the European Community and Hungary on Conformity Assessment and Acceptance of Industrial Products. The Commission negotiated the draft Protocol in accordance with the negotiating guidelines for the negotiation of European Conformity Assessment Agreement with the Central Eastern European Countries, adopted by the Council in June 1997.

The impact on business

The business sectors affected are machinery, electrical safety, electromagnetic compatibility, gas appliances, hot water boilers, medical devices, good laboratory practice (GLP) for medicinal products for human use and medicinal products Good Manufacturing Practice inspection and batch certification.

The PECA provides to extend certain benefits of the Internal Market in industrial sectors already aligned. The PECA permits certification of conformity with technical regulations on product safety, etc, to be conducted in the European Union for exports destined Hungary. This avoids the need for further certification by Hungarian conformity assessment bodies before putting them on the Hungarian market. The certification procedure and the technical regulations are the same as the Community one.

The PECA also envisages acceptance of industrial products that fulfil the requirements to be legally placed on the EU market by Hungary without subject further requirement. Annexes under this mechanism have still to be negotiated.

The PECA therefore presents important advantages from the point of view of transparency, market access, avoidance of duplication especially of cost, effective operation in certain sectors before accession and general facilitation of trade. This is of particular importance for small and medium-sized enterprises. The PECA covers a wide range of sectors and therefore affects an extensive range of firms both large and small. The advantages are not limited to specific geographical areas in the Community.

Businesses will have to apply Hungarian regulations and procedures. However, these are aligned on the EC ones in sectors covered by the PECA. Furthermore, certification, as stated above, will be conducted by conformity assessment bodies located and already designated by the Member States in the Community, and not in Hungary. The PECA will substantially reduce certification costs and improve prospects for exports, employment, investment and competitiveness by Community firms.

The PECA does not contain measures to take account of the specific situation of small and medium-sized firms, but by its nature and by reducing certification costs which are the same for all firms, the agreement will benefit small and medium sized enterprises to a greater extent proportionately than larger firms.

Consultation

The main industry organisations (e.g. EFPIA, Eurobit, and Orgalime) have been consulted and have declared their support for this Protocol.