# COUNCIL DECISION

## of 4 April 2001

## on the conclusion of a 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)

(2001/366/EC)

THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

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 [1], hereinafter referred to as the 'Europe Agreement', entered into force on 1 February 1994.

(2) Article 73(2) of the Europe Agreement provides that cooperation in the fields of standardisation and conformity assessment shall seek to achieve, amongst other things, the conclusion of agreements on mutual recognition.

(3) Article 108(2) 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/Euratom, ECSC, EC, of the Council and the Commission of 13 December 1993 on the conclusion of the Europe Agreement [2], 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 [3] provides that the Association Committee may set up further subcommittees or groups to assist in carrying out its duties.

(6) The Protocol to the Europe Agreement, on Conformity Assessment and Acceptance of Industrial Products, was signed on behalf of the Community in Brussels on 26 February 2001 and should be approved.

(7) Certain tasks for implementation have been conferred upon the Association Council, and in particular, the power to amend the Annexes to the Protocol.

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

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

HAS DECIDED AS FOLLOWS:

*Article 1*

The Protocol to the Europe Agreement, on Conformity Assessment and Acceptance of Industrial Products (hereinafter referred to as 'the Protocol'), as well as the declaration annexed to the Final Act thereto, are hereby approved on behalf of the Community.

The text of the Protocol, and of the declaration annexed to the Final Act thereto 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.

*Article 3*

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

(a) carry into effect 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(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) bring about the consultations, exchange of information, the requests for verifications and for participation in verifications, in accordance with Articles 3, 12 and 14(d), (e), and Section II of the GLP Annex and Sections III and IV of the Annexes to the Protocol concerning machinery, electrical safety, electromagnetic compatibility, hot water boilers, gas appliances, medical devices, GLP and GMP;

(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

[1] OJ L 347, 31.12.1993, p. 2.
[2] OJ L 347, 31.12.1993, p. 1.
[3] OJ L 242, 17.9.1994, p. 23.

compatibility, hot-water boilers, gas appliances, medical devices, GLP and GMP.

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

(a) amendments to the Annexes in accordance with Article 14 point (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 the second and third subparagraphs of Article 11 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 GLP;

(d) the entry into operation of the Sectoral Annex on GLP for medicinal products, in accordance with section IV thereof;

(e) the pre-operational phase and the measures to be taken in accordance with points 3.3, 3.4, 4.12, 4.17 and 5.1 of Section III of the GMP Annex to the Protocol;

(f) 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 Luxembourg, 4 April 2001.

*For the Council*

*The President*

B. ROSENGREN

# 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)

THE EUROPEAN COMMUNITY AND THE REPUBLIC OF 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, Hungarian national law substantially takes over 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 cooperation between them,

DESIRING to conclude a Protocol to the Europe Agreement on Conformity Assessment and Acceptance of Industrial Products (hereinafter referred to as 'this Protocol') providing for the application of the mutual acceptance of industrial products which fulfil the requirements for being 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 of the Europe Agreement and in Protocol 3 thereto,

— '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 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 Hungarian national law.

*Article 3*

**Alignment of legislation**

For the purpose of this Protocol, Hungary agrees to take appropriate measures, in consultation with the Commission of the European Communities, 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 recognise 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 this 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 add new Annexes, 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 to 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 shall be those included in the lists which Hungary and the 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 shall 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 shall 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 shall 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 cooperation 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 the Association 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, coordination and other related activities of the Parties;

(c) encourage their bodies to cooperate 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 responsibilities set out under this Protocol, in conformity with Article 108(2) of the Europe Agreement.

*Article 15*

**Technical cooperation and assistance**

The Community may provide technical cooperation 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 shall constitute an integral part of the Europe Agreement.

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

Hecho en Bruselas, el veintiseis de febrero del dos mil uno.

Udfærdiget i Bruxelles den seksogtyvende februar to tusind og en.

Geschehen zu Brüssel am sechsundzwanzigsten Februar zweitausendundeins.

Έγινε στις Βρυξέλλες, στις είκοσι έξι Φεβρουαρίου δύο χιλιάδες ένα.

Done at Brussels on the twenty-sixth day of February in the year two thousand and one.

Fait à Bruxelles, le vingt-six février deux mille un.

Fatto a Bruxelles, addì ventisei febbraio duemilauno.

Gedaan te Brussel, de zesentwintigste februari tweeduizendeneen.

Feito em Bruxelas, em vinte e seis de Fevereiro de dois mil e um.

Tehty Brysselissä kahdentenakymmenentenäkuudentena päivänä helmikuuta vuonna kaksituhattayksi.

Som skedde i Bryssel den tjugosjätte februari tjugohundraett.

Készült Brüsszelben, 2001. február 26-án.

Por la Comunidad Europea
For Det Europæiske Fællesskab
Für die Europäische Gemeinschaft
Για την Ευρωπαϊκή Κοινότητα
For the European Community
Pour la Communauté européenne
Per la Comunità europea
Voor de Europese Gemeenschap
Pela Comunidade Europeia
Euroopan yhteisön puolesta
På Europeiska gemenskapens vägnar
Az Európai Közösség nevében

Por la República de Hungría
For Republikken Ungarn
Für die Republik Ungarn
Για την Δημοκρατία της Ουγγαρίας
For the Republic of Hungary
Pour la République de Hongrie
Per la Repubblica d'Ungheria
Voor de Republiek Hongarije
Pela República da Hungria
Unkarin tasavallan puolesta
På Republiken Ungerns vägnar
A Magyar Köztársaság nevében

*ANNEXES*

**ANNEXES ON MUTUAL ACCEPTANCE OF INDUSTRIAL PRODUCTS**

*(for the record)*

## 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

5. Gas appliances

6. Medical devices

7. Good Laboratory Practice (GLP) for medicinal products for human use

8. Good Manufacturing Practice (GMP) for medicinal products for human use: inspection and batch certification

*ANNEX ON MUTUAL RECOGNITION OF RESULTS OF CONFORMITY 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, 23.7.1998, p. 1), as amended by European Parliament and Council Directive 98/79/EC of 27 October 1998 (OJ L 331, 7.12.1998, p. 1). |
| 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, 17.4.1998, p. 2606) as last amended by Decree 60/1999 (XII.1) GM (Magyar Közlöny 107, 1.12.1999, 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, 24.2.1999, p. 1036). |

Section II

**Notifying authorities**

*European Community*

| | |
|---|---|
| — Belgium: | Ministère des Affaires Economiques/Ministerie van Economische Zaken. |
| — Denmark: | Direktoratet for Arbejdstilsynet. |
| — Germany: | Bundesministerium für Arbeit und Sozialordnung. |
| — Greece: | Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry). |
| — Spain: | Ministerio de Ciencia y Tecnología. |
| — France: | Ministère de l'emploi et de la solidarité, Direction des relations du travail, Bureau CT 5. |
| — Ireland: | Department of Enterprise and Employment. |
| — Italy: | Ministero dell'Industria, del Commercio e dell'Artigianato. |
| — Luxembourg: | Ministère du Travail (Inspection du travail et des Mines). |
| — Netherlands: | Ministerie van Sociale Zaken en Werkgelegenheid |
| — Austria: | Bundesministerium für Wirtschaft und Arbeit |
| — Portugal: | Under the authority of the Government of Portugal: Instituto Português da Qualidade. |
| — Finland: | Sosiaali-ja terveysministeriö / Social-och hälsovårdsministeriet. |
| — Sweden: | Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC). |
| — 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 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 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 this 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 this 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 Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The 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, 26.3.1973, p. 29), as last amended by Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1). |
| 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, 24.2.1999, p. 1036). |

Section II

**Notifying authorities**

*European Community*

| | |
|---|---|
| — Belgium: | Ministère des Affaires Economiques/Ministerie van Economische Zaken. |
| — Denmark: | Boligministeriet. |
| — Germany: | Bundesministerium für Arbeit und Sozialordung. |
| — Greece: | Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας<br>(Ministry of Development. General Secretariat of Industry). |
| — Spain: | Ministerio de Ciencia y Tecnología. |
| — France: | Ministère de l'économie, des finances et de l'industrie, Direction Générale de l'Industrie, des Technologies de l'Information et des Postes (DiGITIP) − SQUALPI. |
| — 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.<br>Ministère du Travail (Inspection du Travail et des Mines). |
| — Netherlands: | Ministerie van Volksgezondheid, Welzijn en Sport (consumer goods). Ministerie van Sociale Zaken en Werkgelegenheid (others).<br>Ministerie van Sociale Zaken en Werkgelegenheid (others). |
| — Austria: | Bundesministerium für Wirtschaft und Arbeit. |
| — Portugal: | Under the authority of the Government of Portugal: Instituto Português da Qualidade. |
| — Finland: | Kauppa- ja teollisuusministeriö / Handels- och industriministeriet. |
| — Sweden: | Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC). |
| — 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 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 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 this 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 this 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 Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The 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*

## 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, 23.5.1989, p. 19), as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1). |
| 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, 11.6.1999, 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, 24.2.1999, 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, 4.8.1999, p. 4466). |

### Section II

### Notifying authorities

*European Community*

| | |
|---|---|
| — Belgium: | Ministère des Affaires Economiques/Ministerie van Economische Zaken. |
| — Denmark: | Telestyrelsen. |
| — Germany: | Bundesministerium für Arbeit und Sozialordnung. |
| — Greece: | Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας<br>(Ministry of Development. General Secretariat of Industry). |
| — Spain: | Ministerio de Ciencia y Tecnología. |
| — France: | Ministère de l'économie, des finances et de l'industrie, Direction Générale de l'Industrie, des Technologies de l'Information et des Postes (DIGITIP), SQUALPI. |
| — 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: | Ministerie van Verkeer en Waterstaat. |
| — Austria: | Bundesministerium für Wirtschaft und Arbeit. |
| — Portugal: | Under the authority of the Government of Portugal: Instituto Português da Qualidade. |
| — Finland: | Kauppa-ja teollisuusministeriö / Handels-och industriministeriet. For EMC aspects of telecommunications and radio equipment: Liikenne- ja viestintäministeriö/Kommunikationsministeriet. |
| — Sweden: | Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC). |
| — United Kingdom: | Department of Trade and Industry. |

*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 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 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 this 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 this 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 Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The 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-WATER BOILERS**

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 L 167, 22.6.1992 p. 17), as amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1). |
| 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, 17.4.1998, 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, 24.2.1999, p. 1036). |

Section II

**Notifying authorities**

*European Community*

| | |
|---|---|
| — Belgium: | Ministère des Affaires Economiques/Ministerie van Economische Zaken. |
| — Denmark: | Boligministeriet. |
| — Germany: | Bundesministerium für Wirtschaft und Technologie. |
| — Greece: | Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας (Ministry of Development. General Secretariat of Industry). |
| — Spain: | Ministerio de Ciencia y Tecnología. |
| — France: | Ministère de l'économie, des finances et de l'industrie, Direction de l'Action Régionale et de la Petite et Moyenne Industrie (DARPMI). Sous-direction de la sécurité industrielle. |
| — Ireland: | Department of Enterprise and Employment. |
| — Italy: | Ministero dell'Industria, del Commercio e dell'Artigianato. |
| — Luxembourg: | Ministère de l'Environnement. |
| — Netherlands: | Ministerie van Economische Zaken. |
| — Austria: | Bundesministerium für Wirtschaft und Arbeit. |
| — Portugal: | Under the authority of the Government of Portugal: Instituto Português da Qualidade. |
| — Finland: | Ympäristöministeriö/Miljöministeriet. |
| — 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 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 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 this 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 this 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 Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The 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 and national 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, 26.7.1990, p. 15) as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1). |
| 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, 17.4.1998, p. 2629), as last amended by 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, 24.2.1999, p. 1036). |

### Section II

### Notifying authorities

*European Community*

| | |
|---|---|
| — Belgium: | Ministère des Affaires Economiques/Ministerie van Economische Zaken. |
| — Denmark: | Danmarks Gasmateriel Prøvning. |
| — Germany: | Bundesministerium für Arbeit und Sozialordnung. |
| — Greece: | Υπουργείο Ανάπτυξης. Γενική Γραμματεία Βιομηχανίας<br>(Ministry of Development. General Secretariat of Industry). |
| — Spain: | Ministerio de Ciencia y Tecnología. |
| — France: | Ministère de l'économie, des finances et de l'industrie, Direction de l'Action Régionale et de la Petite et Moyenne Industrie (DARPMI). Sous-direction de la sécurité industrielle. |
| — Ireland: | Department of Enterprise and Employment. |
| — Italy: | Ministero dell'Industria, del Commercio e dell'Artigianato. |
| — Luxembourg: | Ministère du Travail (Inspection du Travail et des Mines). |
| — Netherlands: | Ministerie van Economische Zaken. |
| — Austria: | Bundesministerium für Wirtschaft und Arbeit. |
| — Portugal: | Under the authority of the Government of Portugal: Instituto Português da Qualidade. |
| — Finland: | Kauppa-ja teollisuusministeriö/Handels-och industriministeriet. |
| — Sweden: | Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC). |
| — 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 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 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 this 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 this 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 Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The 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, 20.7.1990, p. 17) as last amended by Council Directive 93/68/EEC of 22 July 1993 (OJ L 220, 30.8.1993, p. 1). |
| | Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1) as last amended by European Parliament and Council Directive 98/79/EC of 27 October 1998 (OJ L 331, 7.12.1998, p. 1). |
| National law: | Decree 47/1999 (X.6) EüM of the Ministry of Health on medical devices (Magyar Közlöny 88, 6.10 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, 6.10.1999, p. 5544). |

### Section II

### Notifying authorities

*European Community*

| | |
|---|---|
| — Belgium: | Ministère de la Santé Publique, de l'Environment et de l'Integration Sociale. Inspection Pharmaceutique/Ministerie van Volksgenzondheid, Leefmilieu en Sociale Integratie. Farmaceutische Inspectie |
| | Ministère des Affaires Economiques/Ministerie van Economische Zaken. |
| — Denmark: | Sundhedsministeriet. |
| — Germany: | Bundesministerium für Gesundheit. |
| — Greece: | Υπουργείο Υγείας (Ministry of Health). |
| — Spain: | Ministerio de Ciencia y Tecnología. |
| — France: | Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS). |
| | Ministère de l'économie, des finances et de l'industrie, Direction Générale de l'Industrie, des Technologies de l'Information et des Postes (DIGITIP), Sous-direction de la chimie, de la pharmacie et des biotechnologies. |
| — Ireland: | Department of Health. |
| — Italy: | Ministero della Sanità. |
| — Luxembourg: | Ministère de la Santé. |
| — Netherlands: | Ministerie van Volksgezondheid, Welzijn en Sport; inspectie Volksgezondheid. |
| — Austria: | Bundesministerium für soziale Sicherheit und Generationen. |
| — Portugal: | Under the authority of the Government of Portugal: Instituto Português da Qualidade. |
| — Finland: | Sosiaali-ja terveysministeriö/Social-och hälsovårdsministeriet. |
| — Sweden: | Under the authority of the Government of Sweden: Styrelsen för ackreditering och teknisk kontroll (SWEDAC). |
| — 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 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 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 I, 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 this 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:

1. Where a Party has taken a measure to deny free access to its market for industrial products bearing the CE marking, subject to this 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 this 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 Community to proceed in accordance with the procedure provided for in the Community legislation identified in this Annex.

3. The 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*

## GOOD LABORATORY PRACTICE FOR MEDICINAL PRODUCTS 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 L 15, 17.1.1987, p. 29), as last amended by Commission Directive 1999/11/EC of 8 March 1999 (OJ L 77, 23.3.1999, 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 (OJ L 145, 11.6.1988, p. 35), as last amended by Commission Directive1999/12/EC of 8 March 1999 (OJ L 77, 23.3.1999, p. 22).

*Medicinal products*

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 L 5, 17.1.1987, p. 31).

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 L 15, 17.1.1987, p. 36).

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 L 270, 26.9.1991, p. 32).

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, 6.8.1999, S. 4521).

*Medicinal Products*

Act XXV of 1998 on medicines for human use (Magyar Közlöny 28, 1.4.1998, S. 2385).

### Section II

### Notified Test facilities

For the purpose of this 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 Annex, the term 'Notifying authorities' means the GLP monitoring authorities of the Parties.

*European Community*

| | |
|---|---|
| — 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 (Dänische Arzneimittelbehörde). |
| — Germany: | Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit. |
| — Greece: | Γενικό Χημείο του Κράτους (General Chemical State Laboratory).<br>Υπουργείο Υγείας και Πρόνοιας, Εθνικός Οργανισμός Φαρμάκου) Ministry of Health and Welfare, National Drug Organisation). |
| — Spain: | Agencia Española del Medicamento. |
| — France: | For chemical products other than medicinal products and cosmetics: Groupe interministériel des produits chimiques (GIPC).<br>For medicinal products for human use and cosmetics: Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS). |
| — Ireland: | Irish Laboratory Accreditation Board (ILAB). |
| — Italy: | Ministero della Sanità — Dipartimento della Prevenzione. |
| — Netherlands: | Ministerie van Volksgezondheid, Welzijn en Sport; Inspectie Volkgezondheid. |
| — Austria: | Bundesministerium für Umwelt, Jugend und Familie. |
| — Portugal: | Under the authority of the Government of Portugal: Instituto Português da Qualidade. |
| — Finland: | Sosiaali- ja terveysministeriö / Social- och hälsovårdsministeriet. |
| — Sweden: | Läkemedelsverket (Arzneimittelagentur). |
| — 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 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 requirements 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 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.

*Safeguard clause procedure*

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.

*Cooperation*

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 MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS FOR HUMAN USE: 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, 9.2.1965, p. 369) as last amended by Council Directive 93/39/EEC of 14 June 1993 (OJ L 214, 24.8.1993, p. 22).

Council Directive 75/318/EEC of 20 May 1975 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 proprietary medicinal products (OJ L 147, 9.6.1975, p. 1) as last amended by Commission Directives 1999/82/EEC and 1999/83/EEC of 8 September 1999 (OJ L 243, 15.9.1999, pp. 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, 9.6.1975, p. 13) as last amended by Council Directive 93/39/EEC of 14 June 1993 (OJ L 214, 24.8.1993, 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, 17.7.1991, p. 30).

Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (OJ L 214, 24.8.1993, p. 1) as last amended by Commission Regulation (EC) No 649/98 of 23 March 1998 (OJ L 88, 24.3.1998, p. 7).

Council Directive 92/25/EEC of 31 March 1992 on the wholesale distribution of medicinal products for human use (OJ L 113, 30.4.1992, p. 1) and Guide to Good Distribution Practice.

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

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, 23.3.2000, p. 1206).

Act XXV of 1998 on medicines for human use (Magyar Közlöny 28, 1.4.1998, 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, 19.8.1987, p. 698).

### Section II

### Official GMP inspection services of each party

*European Community*

— Belgium:

Ministère de la Santé Publique, de l'Environment et de l'Intégration Sociale. Inspection Pharmaceutique/Ministerie van Volksgezondheid, Leefmilieu en Sociale Integratie. Farmaceutische Inspectie.

| | |
|---|---|
| — Denmark: | Lægemiddelstyrelsen (Danish Medicines Agency). |
| — Germany: | Bundesministerium für Gesundheit. |
| — Greece: | Υπουργείο Υγείας και Πρόνοιας, Εθνικός Οργανισμός Φαρμάκου (Ministry of Health and Welfare, National Drug Organisation). |
| — Spain: | Agencia Española del Medicamento. |
| — France: | Ministère de l'emploi et de la solidarité, Direction générale de la santé. |
| | Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS). |
| — Ireland: | Irish Medicines Board. |
| — Italy: | Ministero della Sanità. Dipartimento Farmaci e Farmacovigilanza. |
| — Luxembourg: | Direction de la Santé, Division de la Pharmacie et des Médicaments. |
| — Netherlands: | Ministerie van Volksgezondheid, Welzijn en Sport; inspectie Volksgezondheid. |
| — Austria: | Bundesministerium für soziale Sicherheit und Generationen. |
| — Portugal: | Under the authority of the Government of Portugal: Instituto Português da Qualidade. |
| — Finland: | Sosiaali — ja terveysministeriö / Social — och hälsovårdsministeriet. |
| — 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 Community and Hungary as listed in Section I.

'Good Manufacturing Practice (GMP)': as defined in Commission Directive 91/356/EEC and the relevant legislation of Hungary as listed in Section I.

'Inspection': means an on-site evaluation of a manufacturing facility carried out by an inspection service listed in Section II 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.

2. SCOPE AND COVERAGE

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

2.2. For the medicinal products covered by this 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 Community on GMP by Hungary will be determined according to a procedure established by the Community,

— the practical implementation of the requirements of the 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 six months.

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 GMP 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 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, for example 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 Community certification system. 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 (for example 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 (for example 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 (for example 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 (for example '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 control 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:

(a) for the Community:

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

(b) 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 Council 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 Community on the attendance of Hungarian representatives at committee meetings**

In order to ensure a better understanding of the practical aspects of the application of the *acquis communautaire,* the 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 at meetings intended to prepare and issue opinions on implementation 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 Commission.