



## **Protocol to the Convention on the Elaboration of a European Pharmacopoeia<sup>\*</sup>**

Strasbourg, 16.XI.1989

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### **Preamble**

The member States of the Council of Europe which are Parties to the Convention on the Elaboration of a European Pharmacopoeia of 22 July 1964 drawn up within the Council of Europe's Partial Agreement in the Social Public Health Field, hereinafter called "the Convention",

Having regard to the Convention and particularly to the provisions of Article 1 thereof;

Considering that the European Economic Community has adopted rules particularly in the form of directives which apply to the matters covered by the Convention and that it is competent in this field;

Considering therefore that, for the purpose of implementing Article 1 of the Convention, it is necessary for the European Economic Community to be able to become a Party to the Convention;

Considering that, to that end, it is necessary to amend certain provisions of the Convention,

Have agreed as follows:

### **Article 1**

The term "national delegations" in Articles 3 and 5, paragraph 1, of the Convention shall be replaced by the word "delegations".

### **Article 2**

The following text shall replace Article 5, paragraph 3, of the Convention:

"3 The Commission shall elect a Chairman from among its members by secret ballot, by a two-thirds majority of the votes of the delegations. The term of office of the Chairman and the conditions governing his re-election shall be laid down in the Rules of Procedure of the Commission. While he holds office, the Chairman shall not be a member of any delegation."

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(\*) The Treaty of Lisbon amending the Treaty on European Union and the Treaty establishing the European Community entered into force on 1 December 2009. As a consequence, as from that date, any reference to the European Economic Community shall be read as the European Union.

### Article 3

The following text shall replace Article 7 of the Convention:

- "1 Each of the national delegations shall be entitled to one vote.
- 2 On all technical matters, including the order in which the monographs referred to in Article 6 are to be prepared, decisions of the Commission shall be taken by a unanimous vote of national delegations casting votes and a majority of the national delegations entitled to sit on the Commission.
- 3 All other decisions of the Commission shall be taken by a three-quarters majority of the votes cast. For these decisions, from the time of entry into force of the Convention in respect of the European Economic Community, the latter's delegation shall vote in place of its member States' delegations. It shall have a number of votes equal to the number of its member States' delegations.

However, should a Contracting Party alone possess the required majority, the Contracting Parties undertake to renegotiate the voting modalities no sooner than five years after the entry into force of the Protocol, at the request of one of them addressed to the Secretary General of the Council of Europe."

### Article 4

The following text shall be inserted in Article 10 of the Convention, as paragraph 3:

- "3 The conditions of any financial participation by the European Economic Community shall be determined by agreement between the Contracting Parties."

### Article 5

- 1 A new paragraph 3 shall be inserted in Article 12 of the Convention, worded as follows:

"3 The European Economic Community may accede to the present Convention."

- 2 The former paragraph 3 of Article 12 of the Convention shall be renumbered as paragraph 4 of the same article.

### Article 6

A new paragraph 4 shall be inserted in Article 13 of the Convention, worded as follows:

- "4 Paragraphs 1, 2 and 3 above shall apply *mutatis mutandis* to the European Economic Community."

### Article 7

- 1 This Protocol shall be open for signature by the member States of the Council of Europe having signed or acceded to the Convention which may express their consent to be bound by:
  - a signature without reservation as to ratification, acceptance or approval; or
  - b signature subject to ratification, acceptance or approval, followed by ratification, acceptance or approval.

- 2 No member State of the Council of Europe shall sign without reservation as to ratification, acceptance or approval, or deposit an instrument of ratification, acceptance or approval, unless it is already or becomes simultaneously Party to the Convention.
- 3 Any State not a member of the Council of Europe which has acceded to the Convention may also accede to this Protocol.
- 4 Instruments of ratification, acceptance, approval or accession shall be deposited with the Secretary General of the Council of Europe.

**Article 8**

This Protocol shall enter into force on the first day of the month following the expiration of a period of one month after the date on which all Parties to the Convention have expressed their consent to be bound by the Protocol in accordance with the provisions of Article 7.

**Article 9**

The Secretary General of the Council of Europe shall notify the member States of the Council, any other Contracting State to the Convention and the European Economic Community of:

- a any signature;
- b the deposit of any instrument of ratification, acceptance, approval or accession;
- c any date of entry into force of this Protocol in accordance with Article 8;
- d any other act, notification or communication relating to this Protocol.

In witness whereof the undersigned, being duly authorised thereto, have signed this Protocol.

Done at Strasbourg, the 16th November 1989, in English and French, both texts being equally authentic, in a single copy which shall be deposited in the archives of the Council of Europe. The Secretary General of the Council of Europe shall transmit certified copies to each member State of the Council of Europe, to any other Contracting State to the Convention and to the European Economic Community.