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SOCIAL  
HEALTH



Treaty Series No. 8 (1993)

# Protocol

## to the Convention on the Elaboration of a European Pharmacopoeia

Strasbourg, 16 November 1989

[The Protocol entered into force on 1 November 1992]

*Presented to Parliament  
by the Secretary of State for Foreign and Commonwealth Affairs  
by Command of Her Majesty  
February 1993*

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**PROTOCOL  
TO THE CONVENTION ON THE ELABORATION OF  
A EUROPEAN PHARMACOPOEIA**

**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<sup>1</sup> drawn up within the Council of Europe's Partial Agreement in the Social and 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."

**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."

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<sup>1</sup> Treaty Series No. 32 (1974), Cmnd. 5763.

#### 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 day of November 1989, in English and in 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.

## SIGNATURES AND RATIFICATIONS

<i>State</i>	<i>Date of signature</i>	<i>Date of deposit of instrument of ratification, acceptance (A) or approval (a)</i>
Austria ... ..	24 Jul. 1990	22 Aug. 1991
Belgium* ... ..	16 Nov. 1989	4 Apr. 1991
Cyprus* ... ..	3 Dec. 1990	10 Dec. 1991
Denmark† ... ..	16 Nov. 1989	
Finland* ... ..	16 Nov. 1989	14 Jun. 1990 (A)
France* ... ..	29 Nov. 1989	2 Oct. 1990 (a)
Germany* ... ..	22 Jun. 1990	26 Oct. 1990
Greece* ... ..	16 Nov. 1989	27 May 1992
Iceland ... ..	19 Jun. 1990	
Ireland, Republic of ... ..	16 Nov. 1989	
Italy* ... ..	16 Nov. 1989	12 Feb. 1992
Luxembourg* ... ..	16 Nov. 1989	21 May 1991
Netherlands* ... ..	16 Nov. 1989	29 Jan. 1992 (A)
Norway ... ..	16 Nov. 1989	
Portugal* ... ..	16 Nov. 1989	18 Sep. 1992
Spain* ... ..	16 Nov. 1989	27 Jan. 1992
Sweden ... ..	16 Nov. 1989	
Switzerland ... ..	16 Nov. 1989	
United Kingdom* ... ..	16 Nov. 1989	26 Feb. 1991

\* Subject to ratification, acceptance or approval.

† Does not include Greenland and the Faroe Islands.

## RESERVATIONS AND DECLARATIONS

### DENMARK

*On signature:*

Until further notice the signature of Denmark of this Convention does not engage Greenland and the Faroe Islands.

### NETHERLANDS

*On signature:*

The Kingdom of the Netherlands accepts the said Protocol for the Kingdom in Europe, the Netherlands Antilles and Aruba.

