



PROTOCOL
TO THE CONVENTION ON THE ELABORATION
OF A EUROPEAN PHARMACOPOEIA

STRASBOURG, 16.XI.19X9

European Treaty Series
No. 134

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 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.”

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.

For the Government of the Republic of Austria:

For the Government of the Kingdom of Belgium:

*with reservation in respect
of ratification or acceptance*

Mark EYSKENS

For the Government of the Republic of Cyprus:

For the Government of the Kingdom of Denmark:

Uffe ELLEMANN-JENSEN

For the Government of the Republic of Finland:

*with reservation in respect
of ratification or acceptance*

Pertti PAASIO

For the Government of the French Republic:

Strasbourg, le 29 novembre 1989

*with reservation in respect
of ratification or acceptance*

Pierre de BOISDEFFRE

For the Government of the Federal Republic of Germany:

For the Government of the Hellenic Republic:

*with reservation in respect
of ratification or acceptance*

Georges PAPOULIAS

For the Government of the Icelandic Republic:

For the Government of Ireland:

Gerard COLLINS

For the Government of the Italian Republic:

*with reservation in respect
of ratification or acceptance*

Gianni DE MICHELIS

For the Government of the Principality of Liechtenstein:

For the Government of the Grand Duchy of Luxembourg:

*with reservation in respect
of ratification or acceptance*

Jacques F. POOS

For the Government of Malta:

For the Government of the Kingdom of the Netherlands:

with reservation in respect
of ratification or acceptance

Hans van den BROEK

For the Government of the Kingdom of Norway:

Kjell Magne BONDEVIK

For the Government of the Portuguese Republic:

with reservation in respect
of ratification or acceptance

Joao de DEUS PINHEIRO

For the Government of the Republic of San Marino:

For the Government of the Kingdom of Spain:

with reservation in respect
of ratification or acceptance

Pedro SOLBES MIRA

For the Government of the Kingdom of Sweden:

Pierre SCHORI

For the Government of the Swiss Confederation:

René FELBER

For the Government of the Turkish Republic:

For the Government of the United Kingdom of Great Britain and
Northern Ireland:

with reservation in respect
of ratification or acceptance

Francis MAUDE

Sales agents for publications of the Council of Europe

AUSTRALIA / AUSTRALIE
Hunter Publications
58A, Gipps Street
AUS-3066 COLLINGWOOD, Victoria

AUSTRIA / AUTRICHE
Gerold und Co.
Graben 31
A-1011 VIENNA1

BELGIUM / BELGIQUE
La Librairie européenne S.A.
50, avenue Albert-Jonnart
B- 1200 BRUSSELS

CYPRUS / CHYPRE
MAM
The House of the Cyprus Book
P.O. Box 1722
CY-NICOSIA

DENMARK / DANEMARK
Munksgaard
Book and Subscription Service
P.O. Box 2148
DK-1016 COPENHAGEN K

FEDERAL REPUBLIC
OF GERMANY/
RÉPUBLIQUE FÉDÉRALE
D'ALLEMAGNE
Verlag Dr. Hans Heger
HerderstraBe 56
Postfach 20 13 63
D-5300 BONN

FINLAND / FINLANDE
Akateeminen Kirjakauppa
Keskuskatu 1
P.O. Box 128
SF-00101 HELSINKI

GREECE / GRÈCE
Librairie Kauffmann
28, rue Stadiou
GR-ATHENS 132

ICELAND / ISLANDE
Bokabud Mals og mennigar
Laugavegi 18
IS-REYKJAVIK 101

IRELAND / IRLANDE
Government Stationery Office
Publications Section
Bishop Street
IRL-DUBLIN 8

ITALY / ITALIE
Libreria Commissionaria Sansoni
Via Benedetto Fortini, 120/10
Casella Postale 552
I-50125 FLORENCE

MALAYSIA / MALAISIE
Library Building
University of Malaya
P.O. Box 1127
Jalan Pantai Baru
59700 KUALA LUMPUR

NEW ZEALAND /
NOUVELLE-ZÉLANDE
Government Printing Office
Mulgrave Street
(Private Bag)
NZ-WELLINGTON

PAKISTAN
Tayyab M.S. Commercial Services
P.O. Box 16006
A-2/3, Usman Ghani Road
Manzoor Colony
PAK-KARACHI-44

PORTUGAL
Livraria Portugal
Rua do Carmo, 70
P-1200 LISBON

SPAIN / ESPAGNE
Mundi-Prensa Libros S.A.
Castell6 37
E-28001 MADRID

Libreria de la Generalitat
Rambla dels Estudis, 118
E-08002 BARCELONA

SRI LANKA
Centre for Curriculum Advancement
78 Eachamottai Road
CL-JAFFNA

SWEDEN / SUÈDE
Aktiebolaget C.E. Fritzes
Regeringsgatan 12
Box 163 56
S-10327 STOCKHOLM

SWITZERLAND / SUISSE
Buchhandlung Heinemann & Co.
Kirchgasse 17
CH-8001 ZURICH

Librairie Payot
6, rue Grenus
CH- 1211 GENEVA 11

TAIWAN Mappamundi Taiwan 7FI.
258, Nanking E. Rd. Sec. 3 Taipei TAI-
WAN R.O.C.

TURKEY / TURQUIE
Librairie Haset Kitapevi A.S.
469, Istiklâl Caddesi
Beyoglu
TR-ISTANBUL

UNITED KINGDOM /
ROYAUME-UNI
H.M. Stationery Office
Agency Section
51 Nine Elms Lane
GB-LONDON SW8 SDR

UNITED STATES and CANADA/
ÉTATS-UNIS et CANADA
Manhattan Publishing Company
I Croton Point Avenue, P.O. Box 650
CROTON, N.Y. 10520

STRASBOURG
Mésange S.A.
Groupe Berger-Levrault
23, place Broglie
F-67081 STRASBOURG Cedex