



Convention on the Elaboration of a European Pharmacopoeia

Convention relative à l'élaboration d'une pharmacopée européenne

Text amended according to the provisions of the Protocol to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 134), which entered into force on 1 November 1992.

Texte révisé conformément aux dispositions du Protocole à la Convention relative à l'élaboration d'une pharmacopée européenne (STE n° 134), entré en vigueur le 1er novembre 1992.

Strasbourg, 22.VI.1964

— *European Treaty Series*
Série des traités européens / **50**

The Governments of the Kingdom of Belgium, the French Republic, the Federal Republic of Germany, the Italian Republic, the Grand Duchy of Luxembourg, the Kingdom of the Netherlands, the Swiss Confederation and the United Kingdom of Great Britain and Northern Ireland,

Considering that the Parties to the Brussels Treaty of 17th March 1948, as amended on 23rd October 1954, resolved to strengthen the social ties by which they are united and to make every effort in common, both by direct consultation and in specialised Agencies, to raise the standard of living of their peoples and promote the harmonious development of social services in their respective countries;

Considering that the social activities governed by the Brussels Treaty and carried on, until 1959, under the auspices of the Brussels Treaty Organisation and the Western European Union are now conducted within the framework of the Council of Europe, in accordance with the decision taken on 21st October 1959 by the Council of Western European Union and with Resolution (59) 23 adopted on 16th November 1959 by the Committee of Ministers of the Council of Europe;

Considering that the Swiss Confederation has participated since 6th May 1964 in activities in the field of public health carried on under the aforesaid resolution;

Considering that the aim of the Council of Europe is the achievement of greater unity between its members in order to promote, inter alia, economic and social progress by the conclusion of agreements and by common action in economic, social, cultural, scientific, legal and administrative matters;

Considering that, so far as possible, they have endeavoured to promote progress both in the social field and in the related field of public health and that they have undertaken the harmonisation of their national laws in pursuance of the aforementioned provisions;

Considering that such measures are now more than ever necessary in respect of the manufacture, circulation and distribution of medicines in Europe;

Convinced that it is desirable and necessary to harmonise specifications for medicinal substances which, in their original state or in the form of pharmaceutical preparations, are of general interest and importance to the peoples of Europe;

Convinced of the need to hasten the drawing up of specifications for the growing number of new medicinal substances appearing on the market;

Considering that this aim can best be achieved by the progressive establishment of a common pharmacopoeia for the European countries concerned,

Have agreed as follows:

Article 1 - Elaboration of a European Pharmacopoeia

The Contracting Parties undertake:

- a progressively to elaborate a Pharmacopoeia which shall be common to the countries concerned and which shall be entitled «European Pharmacopoeia»;
- b to take the necessary measures to ensure that the monographs which will be adopted by virtue of Articles 6 and 7 of the present Convention and which will constitute the European Pharmacopoeia shall become the official standards applicable within their respective countries.

Article 2 - Organs concerned with the elaboration of the European Pharmacopoeia

The elaboration of the European Pharmacopoeia shall be undertaken by:

- a The Public Health Committee whose activities are carried on within the framework of the Council of Europe, in accordance with Resolution (59) 23 mentioned in the preamble to the present Convention, hereinafter referred to as «the Public Health Committee»;
- b A European Pharmacopoeia Commission established by the Public Health Committee for this purpose, hereinafter referred to as «the Commission».

Article 3 - Composition of the Public Health Committee¹

For the purposes of the present Convention, the Public Health Committee shall be composed of delegations appointed by the Contracting Parties.

Article 4 - Functions of the Public Health Committee¹

- 1 The Public Health Committee shall exercise a general oversight over the activities of the Commission and for this purpose the Commission shall submit a report on each of its sessions to the Public Health Committee.
- 2 All decisions taken by the Commission, other than those of a technical or procedural character, shall be subject to the approval of the Public Health Committee. If the Public Health Committee does not approve a decision or approves it only partially, the committee shall refer it back to the Commission for further consideration.
- 3 The Public Health Committee, having regard to the recommendations of the Commission under Article 6.d, shall fix the time limits within which decisions of a technical character relating to the European Pharmacopoeia shall be implemented within the territories of the Contracting Parties.

Article 5 - Membership of the Commission¹

- 1 The Commission shall be composed of delegations appointed by the Contracting Parties. Each delegation shall consist of not more than three members chosen for their competence in matters within the functions of the Commission. Each Contracting Party may appoint the same number of alternates similarly competent.
- 2 The Commission shall draw up its own Rules of Procedure.

¹ Text amended according to the provisions of the Protocol to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 134), which entered into force on 1 November 1992.

- 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 6 - Functions of the Commission

Subject to the provisions of Article 4 of the present Convention, the functions of the Commission shall be:

- a to determine the general principles applicable to the elaboration of the European Pharmacopoeia;
- b to decide upon methods of analysis for that purpose;
- c to arrange for the preparation of and to adopt monographs to be included in the European Pharmacopoeia; and
- d to recommend the fixing of the time limits within which its decisions of a technical character relating to the European Pharmacopoeia shall be implemented within the territories of the Contracting Parties.

Article 7 - Decisions of the Commission¹

- 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 8 - Seat and meetings of the Commission

- 1 The Commission shall hold its meetings at Strasbourg, the seat of the Council of Europe.
- 2 It shall be convened by its Chairman and meet as often as necessary, but at least twice a year.
- 3 It shall meet in private; the working languages shall be the official languages of the Council of Europe.
- 4 The Public Health Committee may appoint an observer to attend meetings of the Commission.

1. Text amended according to the provisions of the Protocol to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 134), which entered into force on 1 November 1992.

Article 9 - Secretariat of the Commission

The Commission shall have a secretariat, the head and the technical staff of which shall be appointed by the Secretary General of the Council of Europe on the advice of the Commission and in conformity with the Administrative Regulations of the Council of Europe staff. The other members of the secretariat shall be appointed by the Secretary General in consultation with the head of the Commission's secretariat.

Article 10 - Finances¹

- 1 The expenses of the secretariat of the Commission and all other common expenses incurred in the execution of the present Convention shall be borne by the Contracting Parties in accordance with the provisions of paragraph 2 of this article.
- 2 Pending the conclusion of a special arrangement agreed to by all Contracting Parties for this purpose, the financial administration of operations carried out under the present Convention shall be dealt with in accordance with the provisions of the Partial Agreement Budget in the social field relating to the activities covered by Resolution (59) 23 referred to in the preamble to the present Convention.
- 3 The conditions of any financial participation by the European Economic Community shall be determined by agreement between the Contracting Parties.

Article 11 - Entry into force

- 1 The present Convention shall be ratified or accepted by the signatory governments. Instruments of ratification or acceptance shall be deposited with the Secretary General of the Council of Europe.
- 2 The present Convention shall enter into force three months after the date of deposit of the eighth instrument of ratification or acceptance.

Article 12 - Accessions¹

- 1 After the date of the entry into force of the present Convention, the Committee of Ministers of the Council of Europe, sitting with its membership limited to the representatives of the Contracting Parties, may invite, on such conditions as it considers appropriate, any other member State of the Council to accede to the present Convention.
- 2 After the expiry of six years from the said date, the Committee of Ministers may invite, on such conditions as it considers appropriate, European States not members of the Council of Europe to accede to the present Convention.
- 3 The European Economic Community may accede to the present Convention.²
- 4 Accession shall be effected by depositing with the Secretary General of the Council of Europe an instrument of accession, which shall take effect three months after the date of its deposit.

1. Text amended according to the provisions of the Protocol to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 134), which entered into force on 1 November 1992.

2. The Convention as amended by its Protocol entered into force in respect of the European Community on 22 September 1994.

Article 13 - Territorial application'

- 1 Any government may, at the time of signature or when depositing its instrument of ratification, acceptance or accession, specify the territory or territories to which the present Convention shall apply.
- 2 Any government may, when depositing its instrument of ratification, acceptance or accession or at any later date, by declaration addressed to the Secretary General of the Council of Europe, extend the present Convention to any other territory or territories specified in the declaration and for whose international relations it is responsible or on whose behalf it is authorised to give undertakings.
- 3 Any declaration made in pursuance of the preceding paragraph may, in respect of any territory mentioned in such declaration, be withdrawn according to the procedure laid down in Article 14 of the present Convention.
- 4 Paragraphs 1, 2 and 3 above shall apply *mutatis mutandis* to the European Economic Community.

Article 14- Duration

- 1 The present Convention shall remain in force indefinitely.
- 2 Any Contracting Party may, so far as it is concerned, denounce the present Convention by means of a notification addressed to the Secretary General of the Council of Europe.
- 3 Such denunciation shall take effect six months after the date of receipt by the Secretary General of such notification.

Article 15 - Notifications

The Secretary General of the Council of Europe shall notify Contracting States of:

- a any signature;
- b the deposit of any instrument of ratification, acceptance or accession;
- c the date of entry into force of the present Convention in accordance with Article 11;
- d any declaration received in pursuance of the provisions of Article 13;
- e any notification received in pursuance of the provisions of Article 14 and the date on which denunciation takes effect.

Article 16 - Supplementary agreements

Supplementary agreements may be made concerning the detailed implementation of the provisions of the present Convention.

Article 17 - Provisional application

Pending the entry into force of the present Convention in accordance with the provisions of Article 11, the signatory States agree, in order to avoid any delay in the implementation of the present Convention, to apply it provisionally from the date of signature, in conformity with their respective constitutional systems.

1. Text amended according to the provisions of the Protocol to the Convention on the Elaboration of a European Pharmacopoeia (ETS No. 134), which entered into force on 1 November 1992.

In witness whereof the undersigned, being duly authorised thereto, have signed the present Convention.

Done at Strasbourg, this 22nd day of July 1964, in English and French, both texts being equally authoritative in a single copy which shall remain deposited in the archives of the Council of Europe. The Secretary General shall send certified copies to each of the signatory and acceding States.

Sales agents for publications of the Council of Europe

AUSTRALIA/AUSTRALIE

Hunter publications, 58A, Gipps Street
AUS-3066 COLLINGWOOD, Victoria
Fax: (61) 34 19 71 54

AUSTRIA/AUTRICHE

Gerold und Co., Graben 31
A-1011 WIEN 1
Fax: (43) 1512 47 31 29

BELGIUM/BELGIQUE

La Librairie européenne SA
50, avenue A. Jonnart
B-1200 BRUXELLES 20
Fax: (32) 27 35 08 6

Jean de Lannoy

202, avenue du Roi
B-1060 BRUXELLES
Fax: (32) 25 38 08 41

CANADA

Renouf Publishing Company Limited
5369 Chemin Canotek Road
CDN-OTTAWA, Ontario, K1J 9J3
Fax: (1) 613 745 76 60

DENMARK/DANEMARK

Munksgaard
PO Box 2148
DK-1016 KØBENHAVN K
Fax: (45) 33 12 93 87

FINLAND/FINLANDE

Akateeminen Kirjakauppa
Keskuskatu 1, PO Box 218
SF-00381 HELSINKI
Fax: (358) 01 21 44 50

GERMANY/ALLEMAGNE

UNO Verlag
Poppelsdorfer Allee 55
D-53115 BONN
Fax: (49) 228 21 74 92

GREECE/GRÈCE

Librairie Kauffmann
Mavrokordatou 9, GR-ATHINAI 106 78
Fax: (30) 13 23 03 20

HUNGARY/HONGRIE

Euro Info Service
MagyarorQag
Margitsziget (Europa Haz),
H-1138 BUDAPEST
Fax: (36) 1 11162 16
E-mail: eurinfo@mail.mataav.hu

IRELAND/IRLANDE

Government Stationery Office
4-5 Harcourt Road, IRL-DUBLIN 2
Fax: (353) 14 75 27 60

ISRAEL/ISRAEL

ROY International
17 Shimon Hatrssi St.
PO Box 13056
IL-61130 TEL AVIV
Fax: (972) 3 546 1423
E-mail: eurinfo@royil.netvision.net.il

ITALY/ITALIE

Libreria Commissionaria Sansoni
Via Duca di Calabria, 1/1
Casella Postale 552,1-50125 FIRENZE
Fax:(39)55641257

MALTA/MALTE

L. Sapienza & Sons Ltd
26 Republic Street
PO Box 36
VALLETTA CMR 01
Fax: (356) 233 621

NETHERLANDS/PAYS-BAS

InOr-publikaties, PO Box 202
NL-7480 AE HMKSBERGEN
Fax: (31) 542 72 92 96

NORWAY/NORVÈGE

Akademika, A/S Universitetsbokhandel
PO Box 84, Blindern
N-0314 OSLO
Fax: (47) 22 85 30 53

POLAND/ POLOGN E

Gyowna Ksiegarnia Naukowa im. B. Prusa
Krakowskie Przedmiescie 7
PL-00-068 WARSZAWA
Fax: (48) 22 26 64 49

PORTUGAL

Livraria Portugal
Rua do Carmo, 70
P-1200 LISBOA
Fax: (351) 13 47 02 64

SPAIN/ESPAGNE

Mundi-Prensa Libros SA
Castelló 37, E-28001 MADRID
Fax: (34) 15 75 39 98

Llibreria de la Generalitat

Rambla dels Estudis, 118
E-08002 BARCELONA
Fax: (34) 343 12 18 54

SWITZERLAND/SUISSE

BuchLandlung Heinimann & Co.
Kirchgasse 17, CH-8001 ZÜRICH
Fax: (41) 12 51 14 81

BERSY

Route du Manège 60, CP 4040
CH-1950 SION 4
Fax: (41) 27 203 73 32

UNITED KINGDOM/ROYAUME-UNI

HMSO, Agency Section
51 Nine Elms Lane
GB-LONDON SW8 5DR
Fax: (44) 171 873 82 00

UNITED STATES and CANADA/ ÉTATS-UNIS et CANADA

Manhattan Publishine Company
468 Albany Post Road
PO Box 850
CROTON-ON-HUDSON, NY 10520, USA
Fax: (1) 914 271 58 56

STRASBOURG

Librairie Kléber
Palais de l'Europe
F-67075 STRASBOURG Cedex
Fax: +33 (0)3 88 52 91 21