

No. 21200

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**MULTILATERAL**

**Convention on the elaboration of a European Pharmacopoeia. Concluded at Strasbourg on 22 July 1964**

*Authentic texts: English and French.*

**Territorial application by the United Kingdom of Great Britain and Northern Ireland**

*The Convention and the certified statement were registered by the Secretary-General of the Council of Europe, acting on behalf of the Parties, on 1 August 1982.*

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**MULTILATÉRAL**

**Convention relative à l'élaboration d'une pharmacopée européenne. Conclue à Strasbourg le 22 juillet 1964**

*Textes authentiques : anglais et français.*

**Application territoriale par le Royaume-Uni de Grande-Bretagne et d'Irlande du Nord**

*La Convention et la déclaration certifiée ont été enregistrées par le Secrétaire général du Conseil de l'Europe, agissant au nom des Parties, le 1<sup>er</sup> août 1982.*

## CONVENTION<sup>1</sup> ON THE ELABORATION OF A EUROPEAN PHARMACOPOEIA

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,<sup>2</sup> as amended on 23rd October 1954,<sup>3</sup> 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;

<sup>1</sup> Applied provisionally from 1 March 1966, the date on which it had been signed by all the Parties in accordance with article 17 and with reservations made upon signature, and came into force definitively on 8 May 1974, i.e., three months after the date of deposit with the Secretary-General of the Council of Europe of the eighth instrument of ratification or acceptance, in accordance with article 11 (2).

State	Date of deposit of the instrument of ratification or acceptance (A)	State	Date of deposit of the instrument of ratification or acceptance (A)
Belgium .....	26 June 1969	Netherlands .....	3 February 1967
France .....	20 April 1971	(With a declaration of application to the Kingdom in Europe, Surinam and the Netherlands Antilles.)	
Germany, Federal Republic of .....	20 December 1973	Switzerland .....	6 October 1965
(With a declaration of application to <i>Land Berlin</i> .)		United Kingdom of Great Britain and Northern Ireland .....	4 December 1970
Italy .....	7 February 1974		
Luxembourg .....	25 May 1967		

Subsequently, the Convention came into force for the following States, three months after the date of deposit of an instrument of accession with the Secretary-General of the Council of Europe, in accordance with article 12:

State	Date of deposit of the instrument of accession	State	Date of deposit of the instrument of accession
Sweden .....	6 February 1975	Norway .....	21 August 1975
(With effect from 7 May 1975.)		(With effect from 22 November 1975.)	
Denmark .....	18 April 1975	Cyprus .....	7 December 1976
(With effect from 19 July 1975. With a declaration that pending a further decision the Convention would not apply to the Faroe Islands.)		(With effect from 8 March 1977.)	
Iceland .....	10 June 1975	Austria .....	11 July 1978
(With effect from 11 September 1975.)		(With effect from 12 October 1978.)	
		Ireland .....	16 May 1979
		(With effect from 17 August 1979.)	

<sup>2</sup> United Nations, *Treaty Series*, vol. 19, p. 51.

<sup>3</sup> *Ibid.*, vol. 211, p. 342.

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 COMMITTEE*

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

*Article 4. FUNCTIONS OF THE PUBLIC HEALTH COMMITTEE*

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 COMMISSION*

1. The Commission shall be composed of national 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.

3. The Commission shall elect a Chairman from among its members by secret vote. 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, provided that the term of office of the first Chairman shall be three years. While he holds office, the Chairman shall not be a member of any national 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 decision of a technical character relating to the European Pharmacopoeia shall be implemented within the territories of the Contracting Parties.

#### *Article 7. DECISIONS OF THE COMMISSION*

1. Each of the national delegations mentioned in article 5 (1) 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 delegations casting a vote and a majority of the delegations entitled to sit on the Commission.

3. All other decisions of the Commission shall be taken by a two-thirds majority of the votes cast and a majority of the delegations entitled to sit on the Commission.

#### *Article 8. SEAT AND MEETINGS OF THE COMMISSIONS*

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.

#### *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. FINANCES*

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.

#### *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. ACCESSIONS*

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. 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.

#### *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.

#### *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.

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.

For the Government  
of the Kingdom of Belgium:

Cette signature ne produira les effets visés à l'article 17 de la présente Convention qu'à partir du moment où celle-ci aura été signée par toutes les Parties Contractantes.

[This signature will not take effect for the purpose of article 17 of the present Convention until the Convention has been signed on behalf of all Contracting Parties.]<sup>1</sup>

R. COENE

For the Government  
of the French Republic:

Strasbourg, le 29 septembre 1964

Cette signature ne produira les effets visés à l'article 17 de la présente Convention qu'à partir du moment où celle-ci aura été signée par toutes les Parties Contractantes.

[This signature will not take effect for the purpose of article 17 of the present Convention until the Convention has been signed on behalf of all Contracting Parties.]<sup>1</sup>

C. H. BONFILS

For the Government  
of the Federal Republic of Germany:

Strasbourg, le 22 juin 1965

Après signature par toutes les Parties contractantes énumérées au préambule, la République fédérale d'Allemagne appliquera la présente Convention, conformément à son article 17, dès avant son entrée en vigueur, dans la mesure où les lois allemandes en vigueur le permettent.

[After signature by all the Contracting Parties mentioned in the preamble, the Federal Republic of Germany will, in conformity with article 17, apply the present Convention before its entry into force, to the extent possible under applicable German legislation.]<sup>1</sup>

FELICIAN PRILL

<sup>1</sup> Translation supplied by the Council of Europe — Traduction fournie par le Conseil de l'Europe.

For the Government  
of the Italian Republic:

Pour le Gouvernement  
de la République italienne :

Strasbourg, le 11 août 1964

Cette signature ne produira les effets visés à l'article 17 de la présente Convention qu'à partir du moment où celle-ci aura été signée par toutes les Parties Contractantes.

[This signature will not take effect for the purpose of article 17 of the present Convention until the Convention has been signed on behalf of all Contracting Parties.]<sup>1</sup>

ALESSANDRO MARIENI

For the Government  
of the Grand Duchy of Luxembourg:

Pour le Gouvernement  
du Grande Duché de Luxembourg :

Strasbourg, le 2 décembre 1964

Cette signature ne produira les effets visés à l'article 17 de la présente Convention qu'à partir du moment où celle-ci aura été signée par toutes les Parties Contractantes.

[This signature will not take effect for the purpose of article 17 of the present Convention until the Convention has been signed on behalf of all Contracting Parties.]<sup>1</sup>

JEAN WAGNER

For the Government  
of the Kingdom of the Netherlands:

Pour le Gouvernement  
du Royaume des Pays-Bas :

Strasbourg, le 1<sup>er</sup> mars 1966

W. J. D. PHILIPSE

For the Government  
of the Swiss Confederation:

Pour le Gouvernement  
de la Confédération suisse :

Strasbourg, le 22 septembre 1964

Cette signature ne produira les effets visés à l'article 17 de la présente Convention qu'à partir du moment où celle-ci aura été signée par toutes les Parties Contractantes.

[This signature will not take effect for the purpose of article 17 of the present Convention until the Convention has been signed on behalf of all Contracting Parties.]<sup>1</sup>

H. VOIRIER

<sup>1</sup> Translation supplied by the Council of Europe — Traduction fournie par le Conseil de l'Europe.



For the Government  
of the United Kingdom  
of Great Britain and Northern Ireland:  
Strasbourg, 4th September 1964

Pour le Gouvernement du Royaume-Uni  
de Grande-Bretagne et  
et d'Irlande du Nord :

This signature will not take effect for the purpose of article 17 of the present Convention until the Convention has been signed on behalf of all Governments named in the Preamble.

[Cette signature ne produira les effets visés à l'article 17 de la présente Convention qu'à partir du moment où celle-ci aura été signée par tous les gouvernements énumérés au préambule.]

I. F. PORTER

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<sup>1</sup> Traduction fournie par le Conseil de l'Europe — Translation supplied by the Council of Europe.

## TERRITORIAL APPLICATION

*Notification effected to the Secretary-General of the Council of Europe under article 13 (2) of the Convention on the elaboration of a European Pharmacopoeia:*

3 July 1978

UNITED KINGDOM OF GREAT BRITAIN  
AND NORTHERN IRELAND

(In respect of the Isle of Man.)

*Certified statement was registered by the Secretary-General of the Council of Europe, acting on behalf of the Parties, on 1 August 1982.*

## APPLICATION TERRITORIALE

*Notification effectuée au Secrétaire général du Conseil de l'Europe en vertu du paragraphe 2 de l'article 13 de la Convention relative à l'élaboration d'une pharmacopée européenne<sup>1</sup>*

3 juillet 1978

ROYAUME-UNI DE GRANDE-BRETAGNE  
ET D'IRLANDE DU NORD

(A l'égard de l'île de Man.)

*La déclaration certifiée a été enregistrée par le Secrétaire général du Conseil de l'Europe, agissant au nom des Parties, le 1<sup>er</sup> août 1982.*

<sup>1</sup> See p. 69 of this volume.

<sup>1</sup> Voir p. 69 du présent volume.