

K oznámeniu č. 663/2006 Z. z.

CONVENTION on the Elaboration of a European Pharmacopoeia

Strasbourg, 22. VII. 1964

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

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 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 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.

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.¹⁾

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.

Article 13

Territorial application²⁾

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.

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

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.