COMMISSION OF THE EUROPEAN COMMUNITIES

COM(93) 68 final

Brussels, 26 February 1993

Proposal for a

COUNCIL DECISION

accepting, on behalf of the European Economic Community,

the Convention on the elaboration of a European Pharmacopoeia

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. Origin of the European Pharmacopoeia

The Convention on the elaboration of a European Pharmacopoeia, which was signed on 4 September 1964, entered into force in 1974. It currently covers 19 European countries:

- the 12 Member States of the European Community;
- 6 member countries of the European Free Trade Area (EFTA);
- Cyprus.

The ex-USSR, Poland and Hungary have recently indicated their interest in the Convention.

2. Aims of the European Pharmacopoeia

The European Pharmacopoeia forms part of the general framework for the harmonization of national laws on the manufacture, circulation and distribution of medicines in Europe.

The aim of the progressive establishment of a common Pharmacopoeia for the European countries concerned is, as stated in the recitals to the Convention, to:

- "harmonize 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";

- "hasten the drawing up of specifications for the growing number of new medicinal substances appearing on the market."

The harmonized monographs of the European Pharmacopoeia become official technical rules which are applicable in the countries of the Contracting Parties. They are chiefly intended for the pharmaceutical industry and the control authorities as well as, to a lesser extent, dispensing pharmacists.

3. Functioning of the European Pharmacopoeia

The European Pharmacopoeia Commission is instructed to prepare and to adopt technical decisions on the monographs. It consists of eminent scientists appointed by each of the Contracting Parties for their competence and elects a Chairman from among its members. The Public Health Committee of the Council of Europe administratively oversees these activities and in particular lays down the date for implementation of the monographs, although it may not alter any of their technical content.

The work is prepared by a number of groups of experts in conjunction with the Secretariat of the Pharmacopoeia, which has qualified scientific staff and a technical laboratory. The Secretariat also publishes the successive editions of the European Pharmacopoeia and manages and distributes the reference substances to which it refers.

4. Benefit of the European Pharmacopoeia to the Community

From the outset, harmonization of the quality requirements for medicinal substances and preparations has been an objective of both the European Community and the European Pharmacopoeia. The binding nature of the European Pharmacopoeia has been strengthened by Community directives on the testing of proprietary medicinal products for human use and veterinary medicinal products, which include several references to the Pharmacopoeia.

The respective annexes to Council Directive 75/318/EEC[1], as amended, and to Council Directive 81/852/EEC[2], as amended, similarly state that: "The monographs of the European Pharmacopoeia shall apply to all substances appearing in it". This is therefore certainly an area of Community competence, as confirmed at a latter date by the Council during the extension between 1989 and 1992 of Community pharmaceutical regulations to all industrially prepared medicinal products for human or veterinary use.

5. The need for the accession of the European Community

As this is an area of Community competence, it is necessary to regularize the situation by enabling the Community to accede to the Convention on the elaboration of a European Pharmacopoeia by means of an appropriate Protocol. For its part, the Commission regarded accession as an important aspect of its programme for the free circulation of medicinal products and for this reason included in its "White Paper on completing the internal market".

This matter has also been regularly discussed since 1985 in the competent bodies of the European Pharmacopoeia with the participation of a European Community observer. The committees of government experts set up to advise the Commission, in particular the Pharmaceutical Committee, the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products, have helped to consolidate the discussions and consultations with the bodies of the European Pharmacopoeia.

6. The Protocol enabling the Community to accede

By Decision of 26 May 1987, the Council authorized the Commission to conduct negotiations, within the framework of the Council of Europe, to enable the EEC, with its Member States, to accede to the Convention on the elaboration of a European Pharmacopoeia. As the initial version of the Convention was open to individual countries only, the negotiations led to the drafting of

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(1) OJ L 147, 9.6.1975.

(2) OJ L 317, 6.11.1981.

an additional Protocol to enable the EEC to accede to it, the text of which was approved by the Council of the European Communities on 7 March 1988. The Protocol was then signed by the Contracting Parties in November 1989.

The Council of Europe informed the Community that, with the deposit of he last instruments of ratification, the Protocol enabling the Community to become a Contracting Party to the Convention on the European Pharmacopoeia entered into force on 1 November 1992.

7. Contents of the Protocol

As approved by the Council on 7 March 1988, the Protocol in particular lays down the decision-making procedures in the two bodies responsible for the functioning of the European Pharmacopoeia (Public Health Committee and European Pharmacopoeia Commission). After coordination between the Member States of the Community, the European Community, represented by the Commission of the European Communities, exercises the voting rights to which the Member States' delegations are currently entitled.

However, the Community does not vote on the technical matters discussed in the European Pharmacopoeia Commission in order to respect the scientific independence of the delegates who are personally appointed for their technical competence. The Community therefore displays its confidence in the scientific value of the work carried out within the context of the European Pharmacopoeia. It would therefore like to rely fully on the expertise of the members of the European Pharmacopoeia Commission.

8. The proposal for a Decision is accompanied by the text of the Convention on the elaboration of a European Pharmacopoeia, which was signed in 1964, and the Protocol enabling the European Community to accede to it, which entered into force on 1 November 1992. A financial statement on accession is attached to the proposal.

The Commission would ask the Council to adopt the proposal for a Decision accepting, on behalf of the European Economic Community, the Convention on the elaboration of a European Pharmacopoeia.

PROPOSAL FOR A COUNCIL DECISION
accepting, on behalf of the European Economic Community,
the Convention on the elabororation of a European Pharmacopoeia

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THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 113 thereof,

Having regard to the Commission's proposal,

Whereas the Convention on the elaboration of a European Pharmacopoeia, which was drawn up within the Council of Europe, aims to harmonize specifications for medicinal substances and pharmaceutical preparations to enable them to circulate in Europe; whereas the monographs of the European Pharmacopoeia become official technical rules applicable within the territories of the countries which are Contracting Parties to the Convention;

Whereas such measures are now more than ever necessary for the manufacture, circulation and distribution of medicinal products in Europe in order to facilitate trade between the Community and the other Contracting Parties to the Convention;

Whereas, furthermore, the Community has already, in Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmacotoxological and clinical standards and protocols in respect of the testing of medicinal products(1), as last amended by Directive 91/507/EEC of 19 July 1991(2), and Council Directive 81/852/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to analytical, pharmacotoxological and clinical standards and protocols in respect of the testing of veterinary medicinal products(3), as last amended by Directive 92/18/EEC of

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(1) OJ L 147, 9.6.1975, p. 1.

(2) OJ L 270, 26.9.1991, p. 32.

(3) OJ L 317, 6.11.1981, p. 16.

20 March 1992[4], unilaterally recognized the compulsory nature of the European Pharmacopoeia monographs for all products covered by the abovementioned Directives;

HAS DECIDED AS FOLLOWS:

Sole article

The Convention on the elaboration of a European Pharmacopoeia is hereby accepted on behalf of the European Economic Community.

The texts of the Convention and the Protocol enabling the European Economic Community to accede to it are attached to this Decision.

The President of the Council is hereby authorized to notify acceptance to the Council of Europe, the depositary of the Convention and the Protocol, and to designate the persons empowered to sign the Agreement for the purpose of committing the Community to it.

Done at Brussels,

(4) OJ L 97, 14.4.1992, p. 1.

CONVENTION
ON THE ELABORATION
OF A EUROPEAN PHARMACOPOEIA

CONVENTION 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, 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 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 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 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 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.

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 authorized thereto, have signed the present Convention.

Done at Strasbourg, this 22nd day of July 1964 in English and French, both texts being equally athoritative in a 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.

PROTOCOL
TO THE CONVENTION ON THE ELABORATION OF A EUROPEAN PHARMACOPOEIA

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 authorized 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.

FINANCIAL STATEMENT

PROPOSAL FOR A COUNCIL DECISION ON ACCESSION TO THE EUROPEAN PHARMACOPOEIA

SECTION 1: FINANCIAL IMPLICATIONS

1. Title of operation

Accession to the European Pharmacopoeia Convention (Council of Europe)

2. Budget headings involved

B 5-301 Pharmacopoeia

[Reference financial statements previously produced by the Commission:

- SEC(86)2010 - Recommendation for a Council Decision on negotiations with a view to accession to the Pharmacopoeia

- COM(87)697 - (pp. 46.47) Extension of the pharmaceutical directives to medical products not yet covered. (vaccines, blood, radiopharmaceuticals)]

3. Legal basis

- Article 113 of the EEC Treaty

- Commission Directive 91/507/EEC of 19 July 1991 amending the Annex to Council Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal product (OJ L 270, 26.9.1991).

- Commission Directive 92/18/EEC of 20 March 1992 amending the Annex to Council Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products (OJ L 97, 14.4.1992).

4. Description of operation and grounds for accession

The Convention on the elaboration of a European Pharmacopoeia, which was signed in 1964 within the Council of Europe, entered into force in 1974. It currently applies in 19 European countries, including the 12 Community Member States.

The European Pharmacopoeia forms part of the framework for the harmonization of national measures relating to the manufacture and quality control of medicinal products in Europe. The harmonized monographs of the European Phamacopoeia become official requirements applicable within the territories of the Contracting Parties.

As this is an area in which responsibility rests solely with the Community following the adoption of Council Directives 75/318/EEC and 81/352/EEC, it is necessary to regularize the situation by enabling the Community to accede to the Convention on the elaboration of a European Pharmacopoeia by means of an appropriate Protocol. This objective is included in the "White Paper on completing the internal market".

The Protocol, which was approved by the Council on 7 March 1988, has, on 1 November 1992, now been ratified by all of the Contracting Parties. The proposal for a Council Decision is therefore intended to enable the Council, on behalf of the Community, to accept the Convention and the Protocol to it.

Duration: permanent from the date of accession, planned for 1993.

Target population: Community citizens, more than 2 000 pharmaceutical firms and more than 100 000 pharmacists.

5. Classification of expenditure

5.1 Compulsory expenditure

5.2 Differentiated appropriations.

6. Type of expenditure

Annual subsidy towards co-financing of the European Pharmacopoeia. The Pharmacopoeia budget is adopted by the Committee of Ministers of the Council of Europe. The purpose of co-financing is to support the action to be taken on a priority basis to promote the free movement of medicinal products within the Community and the European Economic Area (EEA) such as:

- the faster drawing up of monographs for substances of Community benefit;

- the making of reference standards available to industry;

- collaborative tests between national laboratories for the control of medicinal products;

- biological standardization (vaccines, blood derivatives, etc.).

The normal budget for the European Pharmacopoeia totalled approximately ECU 4 400 000 (FF 30 641 000) in 1992, funded from the contributions paid by the 19 countries which are Contracting Parties to the Convention in accordance with the conventional cost-sharing formula of the Council of Europe (88.5% to be borne by the Community Member States). To this has been added a special supplementary budget of about ECU 450 000 for biological standardization, including ECU 300 000 funded by the Community on the basis of a special contract between the two institutions.

7. Financial impact of the subsidy

(a) For 1993, a contribution of ECU 300 000 for the continuation of the current biological standardization programme is included under item B 5-300. The Act of Accession should normally enter into force around the middle or towards the end of 1993.

In the meantime, the contribution of ECU 300 000 under the current framework contract for biological standardization signed on 22 August 1991 will make it possible to ensure a certain amount of continuity in cooperation between the two institutions in this sector until the end of 1993, given the uncertainty as to the exact date of accession. From 1994, it will be replaced by appropriations under the new heading B 5-301.

(b) From 1994, the Community's overall subsidy to the European Pharmacopoeia under the new budget heading B 5-301 will amount to ECU 750 000 and is intended to cover the following activities:

- ECU 300 000 for the third biological standardization programme;

- ECU 300 000 for tests in cooperation with the national laboratories for the control of medicinal products and to allow the European Pharmacopoeia laboratory to support the new European Medicines Agency;

- ECU 150 000 to speed up the adoption of monographs and methods of analysis for medicinal products of Community benefit and for new categories of such products covered by Community legislation, e.g. homeopathy.

(c) After 1994, the annual subsidy to the European Pharmacopoeia will follow the average rate of increase of 3% of expenditure. The invariable costs will not need to be increased in 1994.

(d) Indicative schedule of commitment appropriations

	1992	1993	1994	1995	1997 and successive years
B 5-300 *	300 000	300 000	-	-	-
B 5-301 **	p.m.	p.m.	750 000	772 500	795 000 (+ 3% per annum)

* Current framework contract signed in July 1991, prior to accession.
** After the Council Decision, planned for the second half of 1993, to accede to the Convention.

8. Anti-fraud measures

The financial control of the Council of Europe, which operates along the same lines as the financial control of the Commission, will see to it that proper procedures are followed in respect of expenditure. The Commission departments will check and approve the subsidies taking account of the Council Decision accepting the Convention and the principles of economy and of sound financial and overall management. The checks will in particular cover the following:

- the preparatory working documents;
- the monographs adopted by the European Pharmacopoeia Commission;
- the official publication of the monographs by the Council of Europe;
- the making of the official reference preparations available to firms and control laboratories.

The Council of Europe will send the Commission of the European Communities full annual reports on the use of the resources, including justification concerning the execution of work.

9. Cost-effectiveness analysis

9.1 Objectives and coherence with financial programming

9.1.1 Specific objectives:

(a) To relaunch and speed up the process of adopting compulsory monographs for the quality of conventional medicinal principals from various sources (generic medicinal products).

(b) To increase the number of monographs from currently 600 (adopted since 1975) to 1 000 by 1995 and 1 500 by the year 2000 so as to facilitate intra-Community trade and trade with the EFTA countries and the developing countries which still apply the standards of the French and British Pharmacopoeias.

(c) To facilitate the drawing up of abridged marketing authorization files containing references to the European Pharmacopoeia.

(d) To produce European reference standards for vaccines and biological products.

9.1.2 These activities are provided for in the financial programming of DG III.

9.1.3 More general objective: to complete the internal market within the pharmaceutical sector. Actions included in the White Paper in 1985.

9.2 Grounds for the operation

The European Pharmacopoeia (Council of Europe, Strasbourg) has laboratories and a highly qualified technical secretariat with a staff of about 40. It arranges nearly 75 meetings of groups of experts a year, with its operating costs limited to expenditure on administration, the laboratories and interpreting.

The Council of Europe works in two official languages (English and French) and does not normally reimburse travel expenses to government experts called to meetings. Its apparent operating costs are therefore relatively low compared with the actual expenditure to be borne by the Contracting Parties to the Convention.

The alternative would be to ask the Member States to withdraw from the Pharmacopoeia Convention and to draw up a Community Pharmacopoeia. This would necessitate the creation of a laboratory infrastructure and the holding of a large number of meetings of experts at Community level and would entail much more expenditure than within the Council of Europe (working languages, travel expenses of experts).

9.3 Monitoring and evaluation of the operation

9.3.1 Accession to the Pharmacopoeia:

Adoption and review, three times a year, of new monographs to be published in the European Pharmacopoeia, in accordance with priorities and a timetable to be agreed in consultation with the Community. Following accession, the Commission will intervene on behalf of the Member States as regards policy decisions on harmonization by the Pharmacopoeia and determination of the priority objectives.

The production of European reference standards to be made available to the European pharmaceutical industry and of monographs to be published in the European Pharmacopoeia.

9.3.2 Performance indicators selected:

Annual activity reports, summary records of the European Pharmacopoeia Commission, official publications of the European Pharmacopoeia.

Individual notifications of results by the Council of Europe to the Commission of the European Communities.

9.3.3 Main factors of uncertainty:

The ability to continue the work in accordance with programmes laid down by the Council of Europe in conjunction with the Community. The need to mobilize a number of government and university experts whose participation is voluntary. This uncertainty would also exist if the work were done by the Community itself.

10. Administrative expenditure for the Commission (part A of the budget)

10.1 Staff

Cooperation with the European Pharmacopoeia will mean increasing the number of permanent staff (under the Staff Regulations) in Unit III/C/3 (Pharmaceuticals), namely:

- 1 A (with pharmaceutical qualifications),
- 1 C

It will be necessary to ensure the appropriate coordination between the work of a number of working parties of experts of the Pharmacopoeia and the bodies to which the Community gives priority, in particular the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products.

10.2 Meetings

The Commission will have to coordinate the position of the Member States of the Community for each of the three sessions of the European Pharmacopoeia Commission currently held and, where necessary, before certain crucial meetings of groups of experts of the Pharmacopoeia.

This will involve additional expenditure on about six meetings a year with the Member States at an estimated cost of ECU 69 000. These will be meetings of institutional committees and their working parties: the Committee for Proprietary Medicinal Products and the Committee for Veterinary Medicinal Products (item A 02510).

10.3 Missions

Provision will have to be made for about 12 missions a year to the steering bodies and to various groups of experts of the Pharmacopoeia which generally meet in Strasbourg, the seat of the Council of Europe. These expenses are estimated at about ECU 5 000 per annum.

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