

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 16 June 1994

accepting, on behalf of the European Community, the Convention on the elaboration of a European Pharmacopoeia

(94/358/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Articles 113 and 100a thereof, in conjunction with the first sentence of Article 228 (2) and the first subparagraph of Article 228 (3),

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament⁽¹⁾,

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, furthermore, in order to facilitate the free circulation of medicinal products inside its territory, the Community has already unilaterally recognized, by Directives 75/318/EEC⁽²⁾ and 81/852/EEC⁽³⁾, the compulsory nature of the European Pharmacopoeia monographs for

all medicinal products covered by Community legislation;

Whereas the Member States are Contracting Parties to the Convention; whereas it might be reasonably expected that a growing number of countries, particularly those of eastern Europe, will accede to the Convention;

Whereas the Community constitutes the principal world exporting zone for medicinal products;

Whereas most medicinal products which circulate between the Community and third countries are the subject of monographs drawn up by the European Pharmacopoeia;

Whereas these monographs should therefore serve as the basis for free circulation of these products between the Community and third countries;

Whereas the Community should therefore accede to the Convention in order to facilitate trade with the other Contracting Parties,

HAS DECIDED AS FOLLOWS:

Article 1

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

The text of the Convention on the Protocol enabling the Community to accede to it are attached to this Decision.

Article 2

The President of the Council shall, on behalf of the Community, deposit the instrument of accession to the Convention with the Council of Europe, which is the depositary of the Convention and the Protocol.

⁽¹⁾ OJ No C 128, 9. 5. 1994.

⁽²⁾ Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (OJ No L 147, 9. 6. 1975, p. 1). Directive as last amended by Directive 93/39/EEC (OJ No L 214, 24. 8. 1993, p. 22).

⁽³⁾ Council Directive 81/852/EEC of 28 September 1981 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 No L 317, 6. 11. 1981, p. 16). Directive as last amended by Directive 93/40/EEC (OJ No L 214, 24. 8. 1993, p. 31).

Article 3

1. Within the Public Health Committee and the European Pharmacopoeia Commission referred to in Article 2 of the Convention, the Community shall be represented by the Commission of the European Communities on the matters referred to in Article 7 (3) of the Convention as amended by Article 3 of the Protocol.

2. The position to be taken within the bodies referred to in paragraph 1 above shall be determined by the Commission in consultation with Member States.

3. The positions to be taken on questions of major importance, in particular with regard to amendments to the obligations on the Member States or when serious

divergencies of views emerge in the consultations envisaged in paragraph 2, shall be determined by the Council acting by qualified majority on a proposal from the Commission.

Done at Luxembourg, 16 June 1994.

For the Council

The President

A. BALTAS