

Opinion of the Economic and Social Committee on the 'Proposal for a Directive of the European Parliament and the Council amending Council Directive 93/42/EEC, as amended by Directive 2000/70/EC, as regards medical devices incorporating stable derivatives of human blood or human plasma'

(2002/C 48/16)

On 15 September 2001 the Council decided to consult the Economic and Social Committee, under Article 95 of the Treaty establishing the European Community, on the above-mentioned proposal.

The Section for Employment, Social Affairs and Citizenship, which was responsible for preparing the Committee's work on the subject, adopted its opinion on 7 November 2001. The rapporteur was Mr Ribeiro, who worked without the assistance of a drafting or study group.

At its 386th plenary session (meeting of 28 November), the Committee adopted the following opinion by 117 votes to one with two abstentions.

1. Introduction

1.1. Directive 2000/70/EC⁽¹⁾ amends Directive 93/42/EEC⁽²⁾ on medical devices by extending its scope to devices incorporating stable derivatives of human blood or human plasma.

1.2. After the approval of the common position by the relevant European Parliament committee — that led to Directive 2000/70/EC⁽³⁾ — Member States drew the Commission's attention to the fact that there was a mistranscription in the wording as agreed by the Council.

1.3. The existence of this mistranscription was ascertained by the experts of all parties involved in the drafting: Council, Parliament, Commission. It was also accepted that the mistranscription might lead to confusion in interpreting the provisions of the Directive, and that the text should be clarified.

1.4. It is against this background that the Commission is proposing this new Directive containing the amendments required to clarify the wording of Directive 2000/70/EC.

(1) Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma, OJ L 313, 13.12.2000.

(2) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, OJ L 169, 12.7.1993.

(3) Opinion of the Economic and Social Committee on the proposal for a Directive of the European Parliament and the Council on in vitro diagnostic medical devices, OJ C 18, 22.1.1996.

2. General comments

2.1. The Economic and Social Committee welcomes the Commission's proposal clarifying the wording of Directive 2000/70/EC.

Brussels, 28 November 2001.

The President
of the Economic and Social Committee
Göke FRERICHS