COUNCIL DIRECTIVE

of 22 December 1986

amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products

(87/19/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the testing of proprietary medicinal products must regularly be adapted to scientific and technical progress in order to ensure optimum protection of public health in the Community;

Whereas, in order to achieve such optimum protection of health, the resources allocated to pharmaceutical research must not be squandered on obsolete or repetitive tests resulting from divergences between the Member States in assessing the state of the art in science and technology;

Whereas, for ethical reasons, it is necessary to replace existing methods as soon as scientific and technical advances so allow by methods involving as few laboratory animals as possible;

Whereas, it is therefore necessary to introduce a rapid procedure for adapting to technical progress the requirements regarding the testing of proprietary medicinal products listed in the Annex to Directive 75/318/EEC (4), as amended by Directive 83/570/EEC (5), whilst ensuring close cooperation between the Commission and the Member States within a 'Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Proprietary Medical Products Sector';

Whereas the requirements relating to the testing of medicinal products must also be capable of rapid revision by the same procedure, having regard to the evolution of test methods and of good laboratory practices recognized by the Community or in international trade in proprietary medicinal products,

(1) OJ No C 293, 5. 11. 1984, p. 4.
(2) OJ No C 36, 17. 2. 1986, p. 152.
(3) OJ No C 160, 1. 7. 1985, p. 18.
(4) OJ No L 147, 9. 6. 1975, p. 1.
(5) OJ No L 332, 28. 11. 1983, p. 1.

HAS ADOPTED THIS DECISION:

Article 1

Directive 75/318/EEC is hereby amended as follows:

1. The following Articles 2a, 2b and 2c shall be inserted:

'Article 2a

Any changes which are necessary in order to adapt the Annex to take account of technical progress shall be adopted in accordance with the procedure laid down in Article 2c.

If appropriate, the Commission shall propose to the Council that the procedure in Article 2c be reviewed in connection with the detailed rules set for the exercise of the powers of implementation granted to the Commission.

Article 2b

1. A Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Proprietary Medicinal Products Sector, hereinafter called "the Committee", is hereby set up; it shall consist of representatives of the Member States with a representative of the Commission as chairman.

2. The Committee shall adopt its own rules of procedure.

Article 2c

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the chairman either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided in Article 148 (2) of the Treaty. The chairman shall not vote.