COUNCIL DIRECTIVE

of 3 May 1989

extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for radiopharmaceuticals

(89/343/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

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

In cooperation with the European Parliament (2),

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

Whereas disparities in the provisions currently laid down by law, regulation or administrative action by Member States may hinder trade in radiopharmaceuticals within the Community;

Whereas the essential aim of any rules governing the production, distributio or use of medicinal products must be to safeguard public health;

Whereas the provisions laid down by Directive 65/65/EEC (4), as last amended by Directive 87/21/EEC (5), and by Second Directive 75/319/EEC (6), as last amended by Directive 83/570/EEC (7), on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products, although appropriate, are inadequate for radiopharmaceuticals;

Whereas, in accordance with Article 5 of Council Directive 87/22/EEC of 22 December 1986 on the approximation of national provisions relating to the placing on the market of high technology medicinal products, particularly those derived from biotechnology (8), the Commission is required to submit proposals to harmonize, along the lines of Directive 75/319/EEC, the conditions for authorizing the manufacture and placing on the market of radiopharmaceuticals before 22 December 1987;

Whereas, in the case of radiopharmaceuticals, generators, kits and precursors, authorization should be required; whereas, however, a specific authorization should not be required for radiopharmaceuticals in their finished form which are made up exclusively from authorized kits, generators or precursor radiopharmaceuticals in health care establishments;

Whereas the Commission should be empowered to adopt any necessary changes in the requirements for the testing of proprietary medicinal products set out in the Annex to Council Directive 75/318/EEC of 20 May 1975 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 proprietary medicinal products (9), as last amended by Directive 87/19/EEC (10), to take account of the special nature of radiopharmaceuticals in close cooperation with the Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Proprietary Medicinal Products Sector, thus ensuring the greater quality, safety and efficacy of the medicinal products;

Whereas any rules governing radiopharmaceuticals must take into account the provisions of Council Directive 84/466/Euratom of 3 September 1984 laying down basic measures for the radiation protection of persons undergoing medical examination or treatment (11); whereas account should also be taken of Council Directive 80/836/Euratom of 15 July 1980 amending the Directives laying down the basic safety standards for the health protection of the general public and workers against the dangers of ionizing radiation (12), as last amended by Directive 84/467/Euratom (13), the objective of which is to prevent the exposure of workers or patients to excessive or unnecessarily high levels of ionizing radiation, and in particular of Article 5c thereof, which requires prior authorization for the addition of radioactive substances to medicinal products as well as for the importation of such medicinal products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. In derogation from Article 34 of Directive 75/319/EEC, and subject to the provisions of this Directive,

(1) OJ No C 36, 8. 2. 1988, p. 30.
(2) OJ No C 290, 14. 11. 1988, p. 136; OJ No C 120, 16. 5. 1989.
(3) OJ No C 208, 8. 8. 1988, p. 64.
(4) OJ No 22, 9. 2. 1965, p. 369/65.
(5) OJ No L 15, 17. 1. 1987, p. 36.
(6) OJ No L 147, 9. 6. 1975, p. 13.
(7) OJ No L 332, 28. 11. 1983, p. 1.
(8) OJ No L 15, 17. 1. 1987, p. 38.
(9) OJ No L 147, 9. 6. 1975, p. 1.
(10) OJ No L 15, 17. 1. 1987, p. 31.
(11) OJ No L 265, 5. 10. 1984, p. 1.
(12) OJ No L 246, 17. 9. 1980, p. 1.
(13) OJ No L 265, 5. 10. 1984, p. 4.