COUNCIL DIRECTIVE

of 24 June 1981

amending Council Directive 78/25/EEC on the approximation of the rules of the Member States relating to the colouring matters which may be added to medicinal products

(81/464/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,

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

Having regard to the opinion of the Economic and Social Committee (2),

Whereas Article 1 of Directive 78/25/EEC (3) stipulates that Member States shall not authorize, for the colouring of medicinal products for human and veterinary use, any colouring matters other than those covered by Annex I, Sections I and II, of the Council Directive of 23 October 1962 on the approximation of the rules of the Member States concerning the colouring matters authorized for use in foodstuffs intended for human consumption (4);

Whereas Section I of the abovementioned Annex covers colouring matter for both mass and surface colouring, and Section II covers colouring matter for surface colouring only;

Whereas there is no justification on public health grounds for maintaining, in the case of medicinal products, the distinction made in the case of foodstuffs intended for human consumption between colouring matter for both mass and surface colouring and colouring matter for surface colouring only;

Whereas Directive 78/25/EEC should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The following paragraph shall be added to Article 1 of Directive 78/25/EEC:

'However, in the case of medicinal products, no distinction shall be made between colouring matter for both mass and surface colouring and colouring matter for surface colouring only.'

Article 2

Member States shall take the measures necessary to comply with this Directive before 1 October 1981 and shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Luxembourg, 24 June 1981.

For the Council

The President

G. M. V. van AARDENNE

(1) OJ No C 4, 7. 1. 1980, p. 46.
(2) OJ No C 113, 7. 5. 1980, p. 36.
(3) OJ No L 11, 14. 1. 1978, p. 18.
(4) OJ No 115, 11. 11. 1962, p. 2645/62.