COMMISSION OF THE EUROPEAN COMMUNITIES

COM(79) 500 final
Brussels, 25 September 1979

Proposal for a
COUNCIL DIRECTVE

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

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(submitted to the Council by the Commission)

Explanatory Memorandum

Council Directive 78/25/EEC of 12 December 1977 relating to the colouring matters which may be added to medicinal products refers to the list of colouring matters authorised for use in foodstuffs intended for human consumption; this list makes a distinction between colouring matter for both mass and surface colouring and colouring matter for surface colouring only.

This distinction - which reduces the alternatives open to a pharmaceuticals industry already subjected to severe technical constraints - is not justified from the point of view of the safeguarding of public health since medicinal products are subjected to a number of prior tests before a marketing authorization is granted.

It would therefore seem desirable to abolish this distinction for medicinal products.

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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,

Having regard to the opinion of the Economic and Social Committee,

Whereas Article 1 of Council Directive 78/25/EEC[1] 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 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[2],

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:

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(1) OJ No L 11, 14.1.1978, p. 18

(2) OJ No 115, 11.11.1962, p. 2645/62

Article 1

The following paragraph is 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

This Directive is addressed to the Member States.