DIRECTIVES

DIRECTIVE 2009/35/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 23 April 2009
on the colouring matters which may be added to medicinal products
(recast)
(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee (1),

Acting in accordance with the procedure laid down in Article 251 of the Treaty (2),

Whereas:

(1) Council Directive 78/25/EEC of 12 December 1977 on the approximation of the laws of the Member States relating to the colouring matters which may be added to medicinal products (3) has been substantially amended several times (4). Since further amendments are to be made, it should be recast in the interests of clarity.

(2) The primary purpose of any laws concerning medicinal products must be to safeguard public health. However, this objective must be attained by means which will not hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.


(4) Those disparities tend to hinder trade in medicinal products within the Community and trade in colouring matters which may be added to those products. Such disparities therefore directly affect the functioning of the internal market.

(5) Experience has shown that there is no reason, on health grounds, why the colouring matters authorised for use in foodstuffs should not also be authorised for use in medicinal products. Consequently, Annex I to Directive 94/36/EC as well as the Annex to Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs (6) should also apply for medicinal products.

(6) However, when the use of a colouring matter in foodstuffs and medicinal products is prohibited in order to safeguard public health, technological and economic disturbances should be avoided as far as is possible. To this end a procedure should be provided for which establishes close cooperation between the Member States and the Commission within a committee for the adjustment to technical progress of the Directives on the elimination of technical barriers to trade in the sector of colouring matters which may be added to medicinal products.

(7) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (7).

(4) See Annex I, Part A.