COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 11.1.2008
COM(2008) 1 final

2008/0001 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the colouring matters which may be added to medicinal products

(Recast)

(presented by the Commission)

EXPLANATORY MEMORANDUM

1. On 1 April 1987 the Commission decided[1] to instruct its staff that all legislative acts should be codified after no more than ten amendments, stressing that this is a minimum requirement and that departments should endeavour to codify at even shorter intervals the texts for which they are responsible, to ensure that the Community rules are clear and readily understandable.

2. The codification of 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[2] has been initiated by the Commission. The new Directive was to have superseded the various acts incorporated in it[3].

3. In the meantime Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[4] has been amended by Decision 2006/512/EC, which introduced a regulatory procedure with scrutiny for measures of general scope designed to amend non-essential elements of a basic instrument adopted in accordance with the procedure referred to in Article 251 of the Treaty, including by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.

4. In accordance with the joint statement of the European Parliament, the Council and the Commission[5] on Decision 2006/512/EC, for this new procedure to be applicable to instruments adopted in accordance with the procedure laid down in Article 251 of the Treaty which are already in force, those instruments must be adjusted in accordance with the applicable procedures.

5. It is therefore appropriate to transform the codification of Directive 78/25/EEC into a recast in order to incorporate the amendments necessary for the adjustment to the regulatory procedure with scrutiny.

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1 COM(87) 868 PV.

2 Carried out pursuant to the Communication from the Commission to the European Parliament and the Council – Codification of the Acquis communautaire, COM(2001) 645 final.

3 See Annex I, Part A of this proposal.

4 OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

5 OJ C 255, 21.10.2006, p. 1.

↓ 78/25/EEC (adapted)

2008/0001 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the colouring matters which may be added to medicinal products

(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[1],

Having regard to the opinion of the European Economic and Social Committee[2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty[3],

Whereas:

⇩ new

(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[4] has been substantially amended several times[5]. Since further amendments are to be made, it should be recast in the interests of clarity.

↓ 78/25/EEC Recital 1

(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

1 OJ C […], […], p. […].
2 OJ C […], […], p. […].
3 OJ C […], […], p. […].
4 OJ L 11, 14.1.1978, p. 18. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
5 See Annex I, Part A.

hinder the development of the pharmaceutical industry or trade in medicinal products within the Community.

↓ 78/25/EEC Recital 2 (adapted)

~~(3)~~ Although Directive ⊠ 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs ⊠[6] established a single list of colouring matters authorised for use in foodstuffs, the disparities between the laws of Member States concerning the colouring of medicinal products still exist.

↓ 78/25/EEC Recital 3 (adapted)

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

↓ 78/25/EEC Recital 4 (adapted)

(5) Experience has shown that on health grounds there is no reason why the colouring matters authorised for use in foodstuffs should not also be authorised for use in medicinal products. Consequently, ⊠ Annex I of Directive 94/36/EC as well as the Annex to Commission Directive 95/45/EC laying down specific purity criteria concerning colours for use in foodstuffs[7] ⊠ should also apply for medicinal products.

↓ 78/25/EEC Recital 5

(6) 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 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.

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[6] OJ L 237, 10.9.1994, p. 13. Directive as last amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

[7] OJ L 226, 22.9.1995, p. 1. Directive as last amended by Directive 2006/33/EC (OJ L 82, 21.3.2006, p. 10).

⇩ new

(7) When enacting this Directive the necessary measures should be put in place in order to conform with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[8].

(8) Power should be conferred on the Commission in particular to amend the limited period of use of medicinal products. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, they should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(9) The new elements introduced into this Directive only concern the committee procedures. They therefore do not need to be transposed by the Member States.

🡻

(10) This Directive should be without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex I, Part B,

🡻 78/25/EEC (adapted)

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Member States shall not authorise, for the colouring of medicinal products for human and veterinary use as defined in Article 1 of ⌦ Directive 2001/83/EC of the European Parliament and of the Council[9] and in Article 1 of Directive 2001/82/EC of the European Parliament and of the Council[10] ⌫ any colouring matters other than those covered by Annex I of Directive 94/36/EC.

[8] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200 of 22.7.2006, p. 11).

[9] OJ L 311, 28.11.2001, p. 67.

[10] OJ L 311, 28.11.2001, p. 1.

↓ 78/25/EEC

Article 2

Member States shall take all measures necessary to ensure that the colouring matters covered by Annex I to the Directive of 94/36/EC satisfy the general and specific criteria of purity laid down in the Annex to Directive 95/45/EC.

↓ 78/25/EEC (adapted)

Article 3

The methods of analysis needed to verify that the general and specific criteria of purity adopted ⌦ pursuant to the first Commission Directive 81/712/EEC[11] are ⌫ satisfied shall also apply for the purpose of this Directive.

↓ 78/25/EEC (adapted)
⇨ new

Article 4

Where a colouring matter is deleted from Annex I to Directive 94/36/EC but the marketing of foodstuffs containing this colouring matter is permitted to continue for a limited period, this provision shall also apply to medicinal products.

This limited period of use may however be amended ⇨ by the Commission ⇦ for medicinal products.

⇨ Those measures designed to amend non-essential elements of this Directive, by completing it, shall be adopted in accordance with the regulatory ⇦ procedure ⇨ with scrutiny ⇦ ⌦ referred to ⌫ in Article 5(2) ⌦ of this Directive ⌫.

[11] OJ L 257, 10.9.1981, p. 1.

↓ 807/2003 Art. 3 Annex III, pt. 25 (adapted)
⇨ new

Article 5

1. The Commission shall be assisted by the committee for the adaptation 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, ⌦ established in accordance with Article 5 of Directive 78/25/EEC ⌫, hereafter referred to as "the committee".

⇨ 2. Where reference is made to this paragraph, Articles 5a(1) to (4) and Article 7 of Decision 1999/468/ECshall apply, in respect to the provisions of Article 8 thereof. ⇦

~~2. Where reference is made to this Article, Articles 5 and 7 of Decision 1999/468/EC[12] shall apply.~~

~~The period set out in Article 5(6) of Decision 1999/468/EC shall be set at three months.~~

~~3. The committee shall adopt its rules of procedure.~~

↓ 78/25/EEC (adapted)

Article 6

↓ 78/25/EEC

Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

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Article 7

Directive 78/25/EEC, as amended by the acts listed in Annex I, Part A is repealed, without prejudice to the obligations of the Member States relating to the time-limits for transposition into national law of the Directives set out in Annex I, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex II.

[12] ~~OJ L 184, 17.7.1999, p. 23.~~

Article 8

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

↓ 78/25/EEC

Article 9

This Directive is addressed to the Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

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ANNEX I

Part A

Repealed Directive with list of its successive amendments
(referred to in Article 7)

Council Directive 78/25/EEC
(OJ L 11, 14.1.1978, p. 18)

Section X, point D, of Annex I of the 1979 Act of Accession
(OJ L 291 of 19.11.1979, p. 108)

Council Directive 81/464/EEC
(OJ L 183, 4.7.1981, p. 33)

Section IX, point C of Annex I of the 1985 Act of Accession
(OJ L 302, of 15.11.1985, p. 217)

Council Regulation (EC) No 807/2003 — Annex III, point 25 only
(OJ L 122,16.5.2003, p. 36)

Part B

List of time-limits for transposition into national law
(referred to in Article 7)

Directive	Time limit for transposition
78/25/EEC	15.6.1979[1]
81/464/EEC	30.9.1981

[1] Pursuant to Article 7(2) of Directive 78/25/EEC: '2. However, any Member State may permit, on its own territory, until the end of a period of four years from the notification of this Directive, the marketing of medicinal products containing colouring matters which do not comply with the requirements of this Directive so long as these colouring matters were authorised in that Member State before the adoption of the Directive.'

ANNEX II

CORRELATION TABLE

Directive 78/25/EEC	This Directive
Article 1, first paragraph	Article 1
Article 1, second paragraph	_____
Articles 2 and 3	Articles 2 and 3
Article 4, first sentence	Article 4, first subparagraph
Article 4, second sentence, first part	Article 4, second subparagraph
Article 4, second sentence, second part	Article 4, third subparagraph
Article 5(1)	_____
Article 6 (1)	Article 5(1)
_____	Article 5(2)
Article 6(2)	_____
Article 6(3)	_____
Article 7(1) to (3)	_____
Article 7(4)	Article 6
_____	Article 7
_____	Article 8
Article 8	Article 9
_____	Annex I
_____	Annex II

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