Basic information

2008/0001(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Colouring matters for medicinal products. Recast Repealing Regulation (EC) No 807/2003, Annex III, point 25 2001/0316 (CNS) **Subject** 4.20.04 Pharmaceutical products and industry	

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
JURI Legal Affairs	SZÁJER József (PPE-DE)	19/12/2007

Committee for opinion	Rapporteur for opinion	Appointed
ENVI Environment, Public Health and Food Safety	ULMER Thomas (PPE-DE)	13/03/2008

Council of the European Union

Council configuration	Meetings	Date
Agriculture and Fisheries	2934	2009-03-23

European Commission

Commission DG	Commissioner
Legal Service	BARROSO José Manuel

Key events

Date	Event	Reference	Summary
11/01/2008	Legislative proposal published	COM(2008)0001	Summary
19/02/2008	Committee referral announced in Parliament, 1st reading		
26/06/2008	Vote in committee, 1st reading		Summary
01/07/2008	Committee report tabled for plenary, 1st reading	A6-0280/2008	
23/09/2008	Decision by Parliament, 1st reading	T6-0431/2008	Summary

23/09/2008	Results of vote in Parliament		
23/03/2009	Act adopted by Council after Parliament's 1st reading		
22/04/2009	End of procedure in Parliament		
23/04/2009	Final act signed		
30/04/2009	Final act published in Official Journal		

Technical information

Procedure reference	2008/0001(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Recast
Legislative instrument	Directive
Amendments and repeals	Repealing Regulation (EC) No 807/2003, Annex III, point 25 2001/0316(CNS)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	JURI/6/58182

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee opinion	ENVI	PE404.618	05/06/2008	
Committee draft report		PE407.752	06/06/2008	
Committee report tabled for plenary, 1st reading/single reading		A6-0280/2008	01/07/2008	
Text adopted by Parliament, 1st reading/single reading		T6-0431/2008	23/09/2008	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03696/2008/LEX	23/04/2009	

European Commission

Document type	Reference	Date	Summary
For information	COM(2007)0740	23/11/2007	
Legislative proposal	COM(2008)0001	11/01/2008	Summary
Commission response to text adopted in plenary	SP(2008)6073	17/10/2008	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES0266/2008	13/02/2008	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Directive 2009/0035
OJ L 109 30.04.2009, p. 0010 Summary

Colouring matters for medicinal products. Recast

2008/0001(COD) - 23/04/2009 - Final act

PURPOSE: to recast 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.

LEGISLATIVE ACT: Directive 2009/35/EC of the European Parliament and of the Council on the colouring matters which may be added to medicinal products (recast).

CONTENT: having reached agreement with the Parliament at first reading, the Council recasts and adapts 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 has been initiated by the Commission. The new Directive was to have superseded the various acts incorporated in it.

In the meantime, Council Decision 1999/468/EC which lays down the procedures for the exercise of implementing powers conferred on the Commission (comitology) 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 codecision procedure.

Consequently, the codification of Directive 78/25/EEC has been transformed into a recast in order to incorporate the amendments necessary for the adjustment to the regulatory procedure with scrutiny.

The new Directive empowers the Commission to amend the limited period of use of medicinal products following the regulatory procedure with scrutiny.

ENTRY INTO FORCE: 20/05/2009.

Colouring matters for medicinal products. Recast

2008/0001(COD) - 11/01/2008 - Legislative proposal

PURPOSE: recast of the 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.

PROPOSED ACT: Directive of the European Parliament and of the Council.

CONTENT: the codification of 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 has been initiated by the Commission. The new Directive was to have superseded the various acts incorporated in it.

In the meantime, Council Decision 1999/468/EC which lays down the procedures for the exercise of implementing powers conferred on the Commission (comitology) 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 codecision procedure.

In accordance with the joint statement of the European Parliament, the Council and the Commission on Decision 2006/512/EC, for this new procedure to be applicable to instruments adopted in accordance with the codecision procedure, those instruments must be adjusted in accordance with the applicable procedures.

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.

Colouring matters for medicinal products. Recast

2008/0001(COD) - 23/09/2008 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted, by 638 votes to 16 with 16 abstentions, a legislative resolution approving the proposal for a directive of the European Parliament and of the Council on the colouring matters which may be added to medicinal products (recast). The report had been tabled for consideration in plenary by József **SZAJER** (EPP-ED, HU) on behalf of the Committee on Legal Affairs. The proposal was approved as adapted to the recommendations of the Consultative Working Party of the Legal Services of the European Parliament, the Council and the Commission.