Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2008/0001(COD)
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	Procedure completed

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	JURI Legal Affairs		19/12/2007
		PPE-DE SZÁJER József	
	Committee for opinion	Rapporteur for opinion	Appointed
	ENVI Environment, Public Health and Food Safety		13/03/2008
		PPE-DE ULMER Thomas	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2934	23/03/2009
European Commission	Commission DG	Commissioner	
	Legal Service	BARROSO José Manuel	

Key events

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	Results of vote in Parliament		
23/09/2008	Decision by Parliament, 1st reading	T6-0431/2008	Summary
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
	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

Document attached to the procedure		COM(2007)0740	23/11/2007	EC	
Legislative proposal		COM(2008)0001	11/01/2008	EC	Summary
Economic and Social Committee: opinion, report		CES0266/2008	13/02/2008	ESC	
Committee opinion	ENVI	PE404.618	05/06/2008	EP	
Committee draft report		PE407.752	06/06/2008	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0280/2008	01/07/2008	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0431/2008	23/09/2008	EP	Summary
Commission response to text adopted in plenary		SP(2008)6073	17/10/2008	EC	
Draft final act		03696/2008/LEX	23/04/2009	CSL	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Directive 2009/35
OJ L 109 30.04.2009, p. 0010 Summary

Colouring matters for medicinal products. Recast

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

The Committee on Legal Affairs adopted a report drafted by József SZAJER (EPP-ED, HU) and approved 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 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.

Colouring matters for medicinal products. Recast

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.

Colouring matters for medicinal products. Recast

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.