Basic information

2006/0295(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Directive	Procedure completed
Community code relating to medicinal products for human use: implementing powers of the Commission Amending Directive 2001/83/EC 1999/0134(COD) **Subject** 4.20.04 Pharmaceutical products and industry	

Key players

European Parliament	**Committee responsible**	**Rapporteur**	**Appointed**
	ENVI Environment, Climate and Food Safety	GROSSETÊTE Françoise (PPE-DE)	27/02/2007
Council of the European Union	**Council configuration**	**Meetings**	**Date**
	Environment	2856	2008-03-03
European Commission	**Commission DG**	**Commissioner**	
	Environment	DIMAS Stavros	

Key events

Date	Event	Reference	Summary
22/12/2006	Legislative proposal published	COM(2006)0919	Summary
17/01/2007	Committee referral announced in Parliament, 1st reading		
26/06/2007	Vote in committee, 1st reading		Summary
05/07/2007	Committee report tabled for plenary, 1st reading	A6-0277/2007	
29/11/2007	Decision by Parliament, 1st reading	T6-0556/2007	Summary
29/11/2007	Results of vote in Parliament		
03/03/2008	Act adopted by Council after Parliament's 1st reading		
11/03/2008	Final act signed		
11/03/2008	End of procedure in Parliament		
20/03/2008	Final act published in Official Journal		

Technical information

Procedure reference	2006/0295(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Directive
	Amending Directive 2001/83/EC 1999/0134(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/44493

Documentation gateway

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE390.464	05/06/2007	
Amendments tabled in committee		PE390.712	14/06/2007	
Committee report tabled for plenary, 1st reading/single reading		A6-0277/2007	05/07/2007	
Text adopted by Parliament, 1st reading/single reading		T6-0556/2007	29/11/2007	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03692/2007/LEX	11/03/2008	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2006)0919	22/12/2006	Summary
Commission response to text adopted in plenary	SP(2007)6527	18/12/2007	

Additional information

Source	Document	Date
National parliaments	IPEX	
European Commission	EUR-Lex	

Final act

Directive 2008/0029
OJ L 081 20.03.2008, p. 0051 Summary

Community code relating to medicinal products for human use: implementing powers of the Commission

2006/0295(COD) - 22/12/2006 - Legislative proposal

PURPOSE: to amend Directive 2001/83/EC on the Community code relating to medicinal products for human use by introducing a reference to the new regulatory procedure with scrutiny(comitology).

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

CONTENT: Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission has been amended by Council Decision 2006/512/EC (CNS/2002/0298).

The amended Decision introduces a new *regulatory procedure with scrutiny* to be used for measures of general scope which seek to amend non-essential elements of a basic instrument, adopted under co-decision, including by deleting some of those elements or by supplementing the instrument by the addition of new non-essential elements.

This procedure allows the legislator to oppose the adoption of "quasi-legislative" measures implementing a codecision-based instrument when it considers that the draft exceeds the implementing powers provided for in the basic instrument, or that the draft is incompatible with the aim or the content of that instrument or fails to respect the principles of subsidiarity or proportionality.

In a joint statement, the three institutions agreed on a list of 26 basic instruments already in force to be adjusted without delay in accordance with the new regulatory procedure with scrutiny (see ACI/2006/2152). Each case has been assessed on its own merits, notably in view of the nature of the implementing powers conferred on the Commission and the specificity of each sector.

Lastly, in accordance with the abovementioned statement, the Commission is proposing to repeal any provisions of these instruments that provide for a time-limit on the delegation of implementing powers to the Commission.

Community code relating to medicinal products for human use: implementing powers of the Commission

2006/0295(COD) - 29/11/2007 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted a resolution drafted by Francoise **GROSSETETE** (EPP-ED, FR) on the proposal amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission. It made some amendments to the Commission's proposal:

- Article 107 was amended to read that the decision on the final measures concerning the product shall be adopted in accordance with the procedure referred to in Article 121(3). Article 107 concerns a particular medicinal product for which a Member State has considered taking regulatory action on pharmacovigilance grounds;

- the rules of procedure of the Standing Committee shall be made public.

Community code relating to medicinal products for human use: implementing powers of the Commission

2006/0295(COD) - 11/03/2008 - Final act

PURPOSE: to amend Directive 2001/83/EC on the Community code relating to medicinal products for human use, by introducing a reference to the new regulatory procedure with scrutiny (comitology).

LEGISLATIVE ACT: Directive 2008/29/EC of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the implementing powers conferred on the Commission.

CONTENT: to recall, Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission has been amended by Council Decision 2006/512/EC (CNS/2002/0298).

The amended Decision introduces a new *regulatory procedure with scrutiny* to be used for measures of general scope which seek to amend non-essential elements of a basic instrument, adopted under co-decision. This may include deleting some of those elements or supplementing the instrument, by the addition of new non-essential elements.

This procedure allows the legislator to oppose the adoption of "quasi-legislative" measures implementing a codecision-based instrument in cases where:

- the draft may exceed the implementing powers provided for in the basic instrument;
- the draft is incompatible with the aim or the content of that instrument; or
- the draft fails to respect the principles of subsidiarity or proportionality.

In a joint statement, the three institutions agreed on a list of 26 basic instruments already in force to be adjusted without delay in accordance with the new regulatory procedure with scrutiny (see ACI/2006/2152). Each case has been assessed on the nature of the implementing powers conferred on the Commission and the specificity of each sector.

The purpose of this act, therefore, is to amend EU legislation relating to medicinal products for human use, by introducing the new *regulatory procedure with scrutiny*.

ENTRY INTO FORCE: 21 March 2008.