Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Directive	2006/0295(COD)
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	Procedure completed

Key players

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

Key events

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	Results of vote in Parliament		
29/11/2007	Decision by Parliament, 1st reading	T6-0556/2007	Summary
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

Legislative proposal		COM(2006)0919	22/12/2006	EC	Summary
Committee draft report		PE390.464	05/06/2007	EP	
Amendments tabled in committee		PE390.712	14/06/2007	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0277/2007	05/07/2007	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0556/2007	29/11/2007	EP	Summary
Commission response to text adopted in plenary		SP(2007)6527	18/12/2007	EC	
Draft final act		03692/2007/LEX	11/03/2008	CSL	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Directive 2008/29
OJ L 081 20.03.2008, p. 0051 Summary

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

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

The Committee on the Environment, Public Health and Food Safety adopted by a large majority the report drafted by Francoise GROSSETETE (EPP-ED, FR) and made three amendments to the Commission?s proposal:

- a new clause was inserted stating that a list of herbal substances, and preparations and combinations of such substances for use in traditional herbal medicinal products, designed to amend non-essential elements of the Directive by supplementing it, must be established in accordance with the regulatory procedure with scrutiny. This list must contain, with regard to each herbal substance, the indication, the specified strength and the posology, the route of administration and any other information necessary for the safe use of the herbal substance as a traditional medicinal product;

- the final measures designed to amend non-essential elements of the Directive by supplementing it shall be adopted in accordance with the regulatory procedure with scrutiny;

- whilst the Commission had proposed the deletion of Article 121(4), the Committee felt that this paragraph should remain, since the comitology committee should be obliged to publish its internal rules.

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

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

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.