Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2006/0207(COD)
Medicinal products for paediatric use: implementing powers conferred on the Commission Amending Regulation (EC) No 1901/2006 2004/0217(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		03/10/2006
		PPE-DE GROSSETÊTE Françoise	
Council of the European Union	Council configuration	Meeting	Date
	Agriculture and Fisheries	2774	19/12/2006
European Commission	Commission DG	Commissioner	
	Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter	

Key events

24/10/2006	Legislative proposal published	COM(2006)0640	Summary
26/10/2006	Committee referral announced in Parliament, 1st reading		
21/11/2006	Vote in committee, 1st reading		Summary
22/11/2006	Committee report tabled for plenary, 1st reading	A6-0396/2006	
14/12/2006	Results of vote in Parliament		
14/12/2006	Decision by Parliament, 1st reading	T6-0592/2006	Summary
19/12/2006	Act adopted by Council after Parliament's 1st reading		
20/12/2006	Final act signed		
20/12/2006	End of procedure in Parliament		
27/12/2006	Final act published in Official Journal		

Technical information

Procedure reference	2006/0207(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
	Amending Regulation (EC) No 1901/2006 2004/0217(COD)
Legal basis	EC Treaty (after Amsterdam) EC 095
Stage reached in procedure	Procedure completed
Committee dossier	ENVI/6/41996

Documentation gateway

Legislative proposal		COM(2006)0640	24/10/2006	EC	Summary
Committee draft report		PE380.764	26/10/2006	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0396/2006	22/11/2006	EP	
Economic and Social Committee: opinion, report		CES1568/2006	13/12/2006	ESC	
Text adopted by Parliament, 1st reading/single reading		T6-0592/2006	14/12/2006	EP	Summary
Draft final act		03677/1/2006	20/12/2006	CSL	
Commission response to text adopted in plenary		SP(2007)0303	24/01/2007	EC	

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Regulation 2006/1902
OJ L 378 27.12.2006, p. 0020 Summary

Medicinal products for paediatric use: implementing powers conferred on the Commission

PURPOSE: to amend a 2006 Regulation of the European Parliament and of the Council on medicinal products for paediatric use and amending Regulation 1768/92/EEC, Directive 2001/20/EC, Directive 2001/83/EC and Regulation 726/2004/EC.

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

CONTENT: Decision 2006/512/EC introduced a new type of procedure for the exercise of implementing powers, the regulatory procedure with scrutiny (see CNS/2002/0298). It is now necessary to apply the 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.

The 2006 Regulation makes provision for implementing powers for the Commission through the regulatory procedure:

- ? in Article 20(2), with a view to further defining the grounds for granting a deferral, and
- ? in Article 49(3), with regard to the maximum amounts as well as the conditions and methods for collection of financial penalties.

Consequently, it is necessary to amend this Regulation in order to make provision for the adoption of these two implementing measures by the new regulatory procedure with scrutiny, as they are intended to supplement the Regulation by the addition of new non-essential elements.

Medicinal products for paediatric use: implementing powers conferred on the Commission

The committee adopted the report by Françoise GROSSETÊTE (EPP-ED, FR) approving unamended - under the 1st reading of the codecision procedure - the proposed regulation amending the new regulation on medicinal products for paediatric use. The proposal was aimed at introducing into the regulation the new regulatory procedure with scrutiny that is now applicable for the exercise of implementing powers.

Medicinal products for paediatric use: implementing powers conferred on the Commission

The European Parliament adopted a resolution drafted by Françoise GROSSETÊTE (EPP-ED, FR) regarding the proposal for amending the regulation on paediatric medicinal products. An agreement was concluded between the institutions giving rise to the quick adoption of this proposal. The plenary adopted three amendments adapting the new regulation to the new rules on comitology regarding the regulatory procedure with scrutiny.

Medicinal products for paediatric use: implementing powers conferred on the Commission

PURPOSE: to amend Regulation (EC) No 1901/2006 on medicinal products for paediatric use so as to align procedures for implementing measures with new rules on comitology (regulatory procedure with scrutiny).

LEGISLATIVE ACT: Regulation (EC) No 1902/2006 of the European Parliament and of the Council

amending Regulation 1901/2006 on medicinal products for paediatric use.

CONTENT: this amending Regulation provides that the measures necessary for the implementation of Regulation (EC) No 1901/2006 should be adopted in accordance with Council Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission. In particular, the Commission is empowered to define further the grounds for granting a deferral for the initiation or completion of some or all of the measures in the paediatric investigation plan and to specify the maximum amounts as well as the conditions and methods for collection of the financial penalties for infringement of the provisions of Regulation (EC) No 1901/2006 or the implementing measures adopted pursuant to it. (Please see COD/2004/0217.)

Since these measures are of general scope and are designed to supplement Regulation (EC) No 1901/2006 by the addition of new non-essential elements, these measures will be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

ENTRY INTO FORCE : 26/01/2007.