Basic information

2006/0207(COD) COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	Procedure completed
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	

Key players

European Parliament	**Committee responsible**	**Rapporteur**	**Appointed**
	ENVI Environment, Public Health and Food Safety	GROSSETÊTE Françoise (PPE-DE)	03/10/2006
Council of the European Union	**Council configuration**	**Meetings**	**Date**
	Agriculture and Fisheries	2774	2006-12-19
European Commission	**Commission DG**	**Commissioner**	
	Internal Market, Industry, Entrepreneurship and SMEs	VERHEUGEN Günter	

Key events

Date	Event	Reference	Summary
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	Decision by Parliament, 1st reading	T6-0592/2006	Summary
14/12/2006	Results of vote in Parliament		
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
Amendments and repeals	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

European Parliament

Document type	Committee	Reference	Date	Summary
Committee draft report		PE380.764	26/10/2006	
Committee report tabled for plenary, 1st reading/single reading		A6-0396/2006	22/11/2006	
Text adopted by Parliament, 1st reading/single reading		T6-0592/2006	14/12/2006	Summary

Council of the EU

Document type	Reference	Date	Summary
Draft final act	03677/1/2006	20/12/2006	

European Commission

Document type	Reference	Date	Summary
Legislative proposal	COM(2006)0640	24/10/2006	Summary
Commission response to text adopted in plenary	SP(2007)0303	24/01/2007	

Other institutions and bodies

Institution/body	Document type	Reference	Date	Summary
EESC	Economic and Social Committee: opinion, report	CES1568/2006	13/12/2006	

Additional information

Source	Document	Date

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

2006/0207(COD) - 14/12/2006 - Text adopted by Parliament, 1st reading/single reading

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

2006/0207(COD) - 24/10/2006 - Legislative proposal

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

2006/0207(COD) - 20/12/2006 - Final act

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.