REGULATION (EC) No 1902/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 December 2006

amending Regulation 1901/2006 on medicinal products for paediatric use

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, in particular Article 95 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee,

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty [1],

Whereas:

(1) The measures necessary for the implementation of Regulation (EC) No 1901/2006 [2] should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [3].

(2) In particular, the Commission should be 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. 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 should be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.

(3) It is necessary to amend Regulation (EC) No 1901/2006 accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1901/2006 is hereby amended as follows:

1) in Article 20, paragraph 2 shall be replaced by the following:

'2. On the basis of the experience acquired as a result of the operation of this Article, the Commission may adopt provisions, in accordance with the regulatory procedure with scrutiny referred to in Article 51(2), amending or supplementing non-essential elements of this Regulation to define further the grounds for granting a deferral.';

2) in Article 49, paragraph 3 shall be replaced by the following:

'3. At the Agency's request, the Commission may impose financial penalties for infringement of the provisions of this Regulation or the implementing measures adopted pursuant to it in relation to medicinal products authorised through the procedure laid down in Regulation (EC) No 726/2004. Measures amending or supplementing non-essential elements of this Regulation concerning the maximum amounts as well as the conditions and methods for collection of those penalties shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 51(2).';

3) in Article 51, paragraph 2 shall be replaced by the following:

'2. Where reference is made to this paragraph, Article 5a (1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.'.

Article 2

This Regulation shall enter into force on the thirtieth day following that of its publication in the *Official Journal of the European Union*.

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[1] Opinion of the European Parliament of 14 December 2006 (not yet published in the Official Journal) and Council Decision of 19 December 2006.

[2] See page 1 of this Official Journal

[3] OJ L 184, 17.7.1999, p. 23. Decision as amended by Decision 2006/512/EC (OJ L 200, 22.7.2006, p. 11).

This Regulation is binding in its entirety and directly applicable in all Member States.

Done at Brussels, 20 December 2006

For the European Parliament	*For the Council*
The President	*The President*
J. BORRELL FONTELLES	J. KORKEAOJA