

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.