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.