

# Medicinal products for paediatric use

2004/0217(COD) - 13/03/2006 - Commission communication on Council's position

The Commission states that it supports the common position. To a very large degree the common position is in line with the Commission's amended proposal. In addition it introduces a small number of changes to the Commission's amended proposal which improve the text while maintaining the initial objectives of the Commission. Many of these modifications concern improvements in the layout of the text or constitute editorial improvements which do not change the meaning or practical application of the Regulation.

Key amendments proposed by the European Parliament in the first reading, such as transparency and membership of the Paediatric Committee, transparency of clinical trials in children, provisions in the event of discontinuation of medicines, funding for studies, labelling of medicines, clearer timelines for procedures, deadlines for the implementation of the regulation, avoiding double rewards and clarifying in what circumstances rewards will be granted, and on review of the paediatric regulation are present in the common position, sometimes with drafting changes to ensure the legal consistency of the text and technical workability of the measures and procedures put in place.