Medicinal products for paediatric use

2004/0217(COD) - 19/07/2006 - Commission opinion on Parliament's position at 2nd reading

The Commission has accepted all of the amendments adopted by the European Parliament, which are the result of a compromise package agreed between the European Parliament and the Council with a view to adopting the Regulation in second reading. The Commission notes that the amendments are in line with the objectives set out in the Commission's initial proposal. The amendments to the Common Position refer to:

- "reward" provisions in the form of a six-month extension of the supplementary protection certificate;

- the introduction of a five-year transition period, following the entry into force of the Regulation, which allows for an extended deadline regarding "supplementary protection certificate" applications;

- a clarification of certain rules and provisions concerning, amongst other things: the independence and impartiality of the Paediatric Committee; publication of the Committee's opinion; pharmacovigilance and risk management; early dialogue between companies developing medicinal products and the Paediatric Committee on whether a product should be developed for children; and preventing delays for the authorisation of medicinal products.

Agreement between the institutions has been facilitated by a Commission declaration made during the June 2006 Plenary session, which states that the Commission will request the "Committee for Medicinal Products for Human Use", to draw up an opinion on the use of carcinogens, mutagens and substances toxic to reproduction as excipients of medicinal products for human use. The Commission will transmit the Committee's Opinion to the European Parliament and the Council. Within six months of the Opinion being finalised the Commission will decide whether or not to take any further action.