COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.7.2006
COM(2006) 408 final

2004/0217 (COD)

OPINION OF THE COMMISSION

pursuant to Article 251 (2), third subparagraph, point (c) of the EC Treaty, on the European Parliament's amendments to the Council's common position regarding the proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004

AMENDING THE PROPOSAL OF THE COMMISSION
in accordance with Article 250 (2) of the EC Treaty

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(Text with EEA relevance)

1. BACKGROUND

Transmission of the proposal to the Council and to the European Parliament - COM(2004) 599 final – 2004/0217 (COD)	22 October 2004
Opinion of the Economic and Social Committee	11 May 2005
Opinion of the European Parliament - first reading	7 September 2005
Transmission of the amended proposal to the Council - COM(2005) 577	10 November 2005
Adoption of the Council common position by qualified majority	10 March 2006
Opinion of the European Parliament - second reading	1 June 2006

2. PURPOSE OF THE PROPOSAL

The initial proposal aimed to address the current situation in Europe whereby more than fifty percent of the medicines used to treat children have not been tested and are not authorised for use in children. The health and therefore quality of life of the children of Europe may suffer from a lack of testing and authorisation of medicines for their use. The overall policy objective was to improve the health of the children of Europe by increasing the research, development and authorisation of medicines for use in children. General objectives were to:

- increase the development of medicines for use in children;
- ensure that medicines used to treat children are subject to high quality research;
- ensure that medicines used to treat children are appropriately authorised for use in children;
- improve the information available on the use of medicines in children, and;

- achieve these objectives without subjecting children to unnecessary clinical trials and in full compliance with Community legislation on clinical trials (Directive 2001/20/EC[1]).

3. OPINION OF THE COMMISSION ON THE AMENDMENTS BY THE EUROPEAN PARLIAMENT

3.1. Summary of the Commission's position

The Commission can accept in full all amendments adopted by the European Parliament. They are the result of a compromise package agreed between the European Parliament and the Council with a view to the adoption of the Regulation in second reading. The amendments are in line with the objectives of the Commission's proposal and maintain the balance of interests achieved in the common position.

The amendments to the Common Position mainly refer to:

- provision for the Commission to adopt guidelines relating to the operation of the reward contained in the Regulation in the form of a six-month extension of the supplementary protection certificate;

- introduction of a transitional period of five years since entry into force reducing the deadline for submission of an application to extend the supplementary protection certificate:

- several clarifications on: the rules on independence and impartiality of members of the Paediatric Committee; the transparency of opinions of this Committee; 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 the avoidance of delays in the authorisation of medicinal products for populations.

The conclusion of the compromise package has been facilitated by a declaration which the Commission made during the June 2006 Plenary session (see annex).

4. CONCLUSION

Pursuant to Article 250(2) of the EC Treaty, the Commission amends its proposal as set out above.

[1] OJ L 121, 1.5.2001, p. 34

ANNEX

Declaration by the Commission:

"In view of the risks of carcinogens, mutagens and substances toxic to reproduction, the Commission will request the Committee for Medicinal Products for Human Use of the European Medicines Agency to draw up an opinion on the use of these categories of substances as excipients of medicinal products for human use, on the basis of Articles 5(3) and 57(1)(p) of Regulation (EC) No 726/2004 of 31 March 2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency.

The Commission will transmit the opinion of the Committee for Medicinal Products for Human Use to the European Parliament and the Council.

Within six-months of the opinion of the Committee for Medicinal Products for Human Use, the Commission will inform the European Parliament and the Council of any necessary action it intends to take to follow-up on this opinion."