



**COUNCIL OF
THE EUROPEAN UNION**

**Brussels, 27 February 2006 (28.02)
(OR. fr,pl)**

**Interinstitutional File:
2004/0217 (COD)**

**6603/06
ADD 1**

**CODEC 167
ECO 25
SAN 37**

ADDENDUM TO "I/A" ITEM NOTE

from : General Secretariat of the Council

to : COREPER/COUNCIL

No. Cion prop. : 13880/04 ECO 168 SAN 157 CODEC 1166
14487/05 ECO 138 SAN 175 CODEC 1019

Subject : Proposal for a Regulation of the European Parliament and of the Council on medicinal products for paediatric use and amending Council Regulation (EEC) No 1768/92, Directive 2001/83/EC and Regulation (EC) No 726/2004

[first reading]

- Adoption (**cp + s**)

(a) of the common position

(b) of the Council's statement of reasons

- Statements

STATEMENT BY THE COUNCIL

The Council states that the funding referred to in Article 40 must be consistent with the financial perspective in force for the period commencing in 2007.

STATEMENT BY THE GERMAN DELEGATION

In addition to the Council's Statement concerning funding, Germany states that the funding referred to in Article 40 must also be consistent with the Community Regulations for funding research.

JOINT STATEMENT BY THE LATVIAN AND BELGIAN DELEGATIONS

Latvia and Belgium welcome the draft proposal, which aims at increasing the development of high-quality medicines for children. Latvia and Belgium agree that a system of rewards and incentives is also necessary to achieve this objective.

At the same time Latvia and Belgium are of the opinion that rewards and incentives should be commensurable with the costs incurred by manufacturers and result in the lowest possible impact on state budget and patients. The main concern of Latvia and Belgium is that the provisions of Articles 36 to 38 of the Regulation will not ensure that the abovementioned objectives will be achieved and could lead to an unjustified increase in the price of medicines, thus reducing access to new high-quality medicines for children.

Latvia and Belgium welcome the inclusion of Article 50(4) in the Regulation and look forward to the evaluation of the results of the application of Articles 36 to 38 within six years of the entry into force of this Regulation.

STATEMENT BY THE POLISH DELEGATION

Poland shares a general objective of the Regulation, which is to promote the development of research into medicines for children, and considers that every effort should be made to provide the paediatric population with medicinal products that are proven to be safe and effective. In our opinion, it is particularly important to ensure full access to paediatric medicines – including those which are refundable under the national health care scheme – at the earliest possible stage.

Consequently, the extension of protection periods for original products, as proposed in Articles 36, 37 and 38 of the Regulation, is impossible for Poland to accept since it delays the marketing of cheaper generic products, thereby restricting patients' access to pharmacotherapy and increasing expenditure in national health care budgets. Poland considers that this conflicts with the overriding aim of this Regulation, which is to provide children in Europe with safe and effective medicines. Poland therefore votes against political agreement on a common position concerning the proposal for a Regulation.

Poland awaits a review of the system of rewards and incentives pursuant to Articles 36, 37 and 38, and trusts that the functioning of such a system will be analysed in detail within six years of the entry into force of this Regulation. Poland will welcome any amendments which guarantee the proportionality of the system of rewards and incentives and ensure that greater consideration is given to the costs of treatment borne by patients and national budgets.