



**COUNCIL OF
THE EUROPEAN UNION**

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

6603/06

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"I/A" ITEM NOTE

from: General Secretariat of the Council
to: COREPER/COUNCIL

Nos Cion props: 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 Regulation (EEC) No 1768/92, Directive 2001/83/EC and Regulation (EC) No 726/2004
[first reading]
– Adoption of **(cp + s)**
(a) a common position
(b) a statement of the Council's reasons

1. On 22 October 2004 the Commission sent the Council the above proposal ¹, based on Article 95 of the EC Treaty.
2. The Economic and Social Committee delivered its opinion ² on 11 May 2005.
3. The European Parliament delivered its first-reading opinion ³ on 7 September 2005, passing 69 amendments to the Commission proposal.

¹ 13880/04.

² OJ C 267, 27.10.2005, p. 1.

³ 11956/05.

4. The Commission submitted an amended proposal ¹, under Article 250(2) of the EC Treaty, on 11 November 2005.
5. At its 2699th meeting, on 8 and 9 December 2005, the Council (Employment, Social Policy, Health and Consumer Affairs) reached political agreement on a common position on the above Regulation.
6. The Permanent Representatives Committee is asked to advise the Council to:
 - adopt the common position in 15763/05 and the statement of reasons in 15763/05 ADD 1, as an "A" item at a forthcoming meeting, with the Polish delegation voting against them;
 - have the statements in the addendum hereto entered in the minutes of that meeting.



¹ 14487/05.