COUNCIL OF THE EUROPEAN UNION

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"I/A" ITEM NOTE

from :	General Secretariat
to :	Permanent Representatives Committee/Council
No. Cion prop.:	6292/12 MI 86 PHARM 5 SAN 23
Subject:	Draft COMMISSION REGULATION (EU) No …/.. of XXX amending Regulation (EC) No 658/2007 concerning financial penalties for infringement of certain obligations in connection with marketing authorisations granted under Regulation (EC) No 726/2004 of the European Parliament and of the Council – *Decision not to oppose adoption*

1. Article 84(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council 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[1] and Article 49(3) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 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[2] both provide that the Commission may impose financial penalties for infringement of the provisions of those Regulations or implementing measures adopted pursuant to those Regulations. Those Articles furthermore provide that the maximum amounts as well as the conditions and methods for collection of these penalties shall be laid down by the Commission in accordance with the regulatory procedure with scrutiny.

[1] OJ L 136, 30.4.2004, p. 1.
[2] OJ L 378, 27.12.2006, p. 1.

2. The Regulatory procedure with scrutiny is laid down in Article 5a of Council Decision 1999/468/EC ("the Comitology Decision") as amended by Council Decision 2006/512/EC[3].

3. According to the second subparagraph of Article 12 of Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers[4], the effects of Article 5a of the Comitology Decision are maintained for the purposes of existing basic acts making reference thereto.

4. The Commission has, in accordance with Article 84(3) of Regulation (EC) No 726/2004 and Article 49(3) of Regulation (EC) No 1901/2006, prepared a draft Regulation[5] to update Commission Regulation (EC) No 658/2007.

5. Before adopting the draft Regulation and in accordance with Article 5a(2) of the Comitology Decision, the Commission consulted the Standing Committee on Medicinal Products for Human Use[6] and of the Standing Committee on Veterinary Medicinal Products[7]. Both voted in favour of the draft Regulation.

6. Consequently, the Commission submitted the draft Regulation to the Council on 7 February 2012, in accordance with Article 5a(3)(a) of the Comitology Decision.

7. Under the regulatory procedure with scrutiny, the Council, acting by qualified majority, may oppose the Commission's adoption of the draft Commission Regulation on the grounds that the draft measures presented by the Commission:
   - exceed the implementing powers provided for in the basic instrument, or
   - are not compatible with the aim or the content of the basic instrument, or
   - do not respect the principles of subsidiarity or proportionality.

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3 OJ L 200 22.7.2006 p.11.
4 OJ L 55, 28.2.2011, p. 13.
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6 Voting date 23 January 2012, 290 votes in favour, no abstentions, no votes against.
7 Voting date 23 January 2012, 269 votes in favour, no abstentions, no votes against.

8. The delegations were asked on 10 February 2012 to indicate until 28 February 2012 their possible opposition to the draft Regulation. The delegations did not raise any of the above-mentioned grounds for opposition.

9. **The Permanent Representatives Committee is therefore invited to recommend to the Council to confirm, as an "A" item of its agenda, that it is not opposed to the draft Regulation in subject.**