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"I/A" ITEM NOTE

From :	General Secretariat of the Council
to :	Permanent Representatives Committee/Council
No. prev. doc. :	9425/12 PHARM 30 SAN 92 MI 277
Subject :	Draft COMMISSION REGULATION (EU) No …/.. of XXX amending Commission Regulation (EC) No 1234/2008 concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products - Preparation of a Council Decision

1. Article 27b of Directive 2001/82/EC on the Community code relating to veterinary medicinal products[1], Article 23b(1) of Directive 2001/83/EC on the Community code relating to medicinal products for human use[2] as well as Article 16(4) and Article 41(6) of Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[3], all provide that the Commission shall adopt provisions for the examination of variations to marketing authiorisations in the form of a regulation. They further provide that that regulation shall be adopted in accordance with the regulatory procedure with scrutiny.

1 OJ L 311. 28.11.2001, p. 1.
2 OJ L 311. 28.11.2001, p. 67.
3 OJ L 136. 30.4.2004, p. 1.

2. The regulatory procedure with scrutiny was regulated by Article 5a of the Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission[4].

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[5], the effects of Article 5a of the Decision 1998/468/EC are maintained for the purposes of existing basic acts making reference thereto.

4. The Commission has, in accordance with Article 27b of Directive 2001/82/EC, Article 23b(1) of Directive 2001/83/EC and Articles 16(4) and 41(6) of Regulation (EC) No 726/2004, prepared a draft Regulation[6] to update Commission Regulation (EC) No 1234/2008[7] concerning the examination of variations to the terms of marketing authorisations for medicinal products for human use and veterinary medicinal products.

5. The draft Commission Regulation is consistent with the opinions of the Standing Committee on Medicinal Products for Human Use[8] and of the Standing Committee on Veterinary Medicinal Products[9], which voted by unanimity in favour of the above draft Regulation.

6. Consequently, the Commission submitted the above draft Regulation to the Council on 11 April 2012, in accordance with Article 5a(3)(a) of Council Decision 1999/468/EC.

7. The Council may oppose the draft Commission Regulation by qualified majority only if:
   i) it exceeds the implementation powers provided for by the basic instrument, or
   ii) it is not compatible with the aim or the content of the basic instrument, or
   iii) it does not respect the principles of subsidiarity or proportionality.

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4 OJ L 184, 17.7.1999, p. 23.
5 OJ L 55, 28.2.2011, p. 13.
6 9425/12 PHARM 30 SAN 92 MI 277.
7 OJ L 334, 12.12.2008, p. 7.
8 Voting date 27 March 2012, 323 votes in favour, no abstentions, no votes against.
9 Voting date 27 March 2012, 330 votes in favour, no abstentions, no votes against.

8. In the meeting of the Working Party on Pharmaceuticals and Medical devices on 16 May 2012, delegations were asked to indicate before 31 May 2012 their possible opposition to the draft Regulation. No delegation raised 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.** Unless the European Parliament opposes the Regulation within 3 months from its submission, the Commission may adopt it in accordance with the procedure under Article 5a(3)(d) of Council Decision 1999/468/EC.