COUNCIL OF THE EUROPEAN UNION

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"I/A" ITEM NOTE

From :	General Secretariat of the Council
to :	Permanent Representatives Committee/Council
No. prev. doc. :	9264/12 PHARM 28 SAN 89 MI 270
Subject :	Draft COMMISSION REGULATION (EU) No .../.. of XXX concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin - Preparation of a Council Decision

1. Article 10c of Council Directive 90/385/EEC on the approximation of laws of the Member States relating to active implantable medical devices[1] and Article 14b of Council Directive 93/42/EEC concerning medical devices[2], both provide that the Commission may adopt measures relating to the introduction of particular requirements in order for a certain group of medical devices to be put on the market. They further provide that those measures shall be adopted in accordance with the regulatory procedure with scrutiny.

[1] OJ L 189, 20.7.1990, p. 17.
[2] OJ L 169, 12.7.1993, 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[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 Decision 1998/468/EC are maintained for the purposes of existing basic acts making reference thereto.

4. The Commission has, in accordance with Article 10c of Council Directive 90/385/EEC and Article 14b of Council Directive 93/42/EEC, prepared a draft Regulation[5] that replaces Commission Directive 2003/32/EC introducing detailed specifications as regards the requirements laid down in Council Directive 93/42/EEC with respect to medical devices manufactured utilising tissues of animal origin[6].

5. The draft Commission Regulation is consistent with the opinion of the Committee on the approximation of the laws of the Member States relating to Medical devices[7], which voted by unanimity in favour of the above draft Regulation.

6. Consequently, the Commission submitted the above draft Regulation to the Council on 16 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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3 OJ L 184, 17.7.1999, p. 23.
4 OJ L 55, 28.2.2011, p. 13.
5 9425/12 PHARM 30 SAN 92 MI 277.
6 OJ L 105, 24.4.2003, p. 18.
7 Voting date 31 January 2012, 345 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 7 June 2012 their possible opposition to the draft Regulation. No delegation raised any of the above-mentioned grounds for opposition. The French delegation has however entered a parliamentary scrutiny reserve, indicating that it could be lifted in the beginning of July.

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.