



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 17 December 2012

17856/12

**PHARM 92
SAN 333
MI 837
AGRILEG 191**

"A" ITEM NOTE

from: General Secretariat
to: Council

No. prev. doc.: 15798/12 PHARM 79 SAN 267 MI 692 AGRILEG 163

Subject: Appointment of four members of the Management Board of the European
Medicines Agency (EMA)

1. Article 65(1) of Regulation (EC) No 726/2004 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 provides that the Council, in consultation with the European Parliament and on the basis of a list drawn up by the Commission, shall appoint two representatives of patients' organisations, one representative of doctors' organisation and one representative of veterinarians' organisations as members of the Management Board of the European Medicines Agency (EMA).

2. On 8 August 2012, the Commission adopted a Decision¹ setting out a list of candidates relating to the nomination of four members of the EMA Management Board. The Commission sent the Decision to the Council and the European Parliament and also provided the curricula vitae of the candidates.
3. On 16 November 2012, the Council Secretariat issued a document² explaining the procedure for appointment of the four members of the Management Board and correcting the candidate list following information from the Commission services.
4. On 21 November 2012, the European Parliament issued an official letter³, recommending six of the candidates.
5. On 14 December 2012, the Permanent Representatives Committee in a secret ballot selected two representatives of patients' organisations, one representative of doctors' organisation and one representative of veterinarians' organisations. Since Article 16(3) of the Treaty on European Union⁴ provides that a qualified majority is required for these appointments it was then checked whether any delegation would object to the appointment of the four candidates thus selected. No delegation objected.
6. The Permanent Representatives Committee further agreed to recommend that the EMA Management Board decide the date on which their period as members of the Management Board will commence and that the Decision be published in the Official Journal of the European Union.

¹ Commission document C(2012) 5562 final. Council document 11966/12 PHARM 55 SAN 166 MI 460 AGRILEG 135.

² Document 15798/12 PHARM 79 SAN 267 MI 692 AGRILEG 163.

³ Document 15799/12 PHARM 80 SAN 268 MI 693 AGRILEG 164.

⁴ "The Council shall act by a qualified majority except where the Treaties provide otherwise."

Consequently, **the Council** is invited:

- to adopt the Decision set out in document 16554/1/12 REV 1 PHARM 84 SAN 284 MI 761 AGRILEG 192⁵

and

- to have that Decision published in the Official Journal of the European Union.
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⁵ Document as finalised by the legal-linguists.