



**COUNCIL OF
THE EUROPEAN UNION**

Brussels, 16 November 2012

15798/12

**PHARM 79
SAN 267
MI 692
AGRILEG 163**

NOTE

from: General Secretariat
to: Permanent Representatives Committee (Part 1)
No. prev. doc.: 11966/12 PHARM 55 SAN 166 MI 460 AGRILEG 135
Subject: Appointment of four members of the Management Board of the European
Medicines Agency (EMA)
- Procedure

A. INTRODUCTION

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, in addition to one representative of each Member State, two representatives of the Commission and two representatives of the European Parliament, two representatives of patients' organisations, one representative of doctors' organisation and one representative of veterinarians' organisations shall be appointed as members of the EMA Management Board by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission. It further provides that the European Parliament may submit its views to the Council for consideration, which shall then appoint the members of the Management Board.

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 Management Board of the European Medicines Agency. The Commission sent the Decision to the Council and the European Parliament and also provided the curricula vitae of the candidates.
3. The Council Secretariat has sent a letter² with an Annex containing the list of candidates together with the curricula vitae of the candidates directly to the Deputy Permanent Representatives and to the Health Attachés.
4. An official letter³, in which the European Parliament informs the Council of which of the candidates on the list it recommends is expected to be issued shortly. The letter will list one candidate representing doctors, one candidate representing veterinarians and two candidates in order of recommendation representing patients.
5. The Commission has proposed three candidates⁴ for the post of Management Board member representing doctors. The European Parliament is expected to recommend one of them for appointment.
6. The Commission has proposed two candidates⁵ for the post of Management Board member representing veterinarians. The European Parliament is expected to recommend one of them for appointment.
7. The Commission has proposed six⁶ candidates for the post of Management Board member representing patients, of these candidates the European Parliament is expected to retain two, in order of preference, for consideration by the Council.

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

² The letter contains a list that has been corrected to reflect a forthcoming Commission Decision necessary to correct some mistakes in the original list.

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

⁴ See Annex II.

⁵ See Annex II.

⁶ See Annex II. Please note that one of the candidates has withdrawn.

B. PROCEDURE

8. Under Article 16(3) of the Treaty on European Union⁷, a **qualified majority** is required for these appointments.
9. The Council must select one representative for doctors from three candidates, one representative for veterinaries from two candidates and two representatives for patients among five candidates.
10. In order to establish a simple procedure for finding out which candidates have the strongest support, it is proposed to follow the procedure outlined in point 12⁸. A decision by the Permanent representatives Committee to use that procedure could, in accordance with Article 240(3) of the Treaty on the functioning of the European Union⁹, be adopted by a **simple majority** of its members.
11. The Committee could then verify that a qualified majority of its members (255 votes in favour) could support a decision to recommend to the Council to appoint the candidates that received the strongest support.

⁷ "The Council shall act by a qualified majority except where the Treaties provide otherwise."

⁸ That procedure was used in previous appointments of members of the EMA management board. See *e.g.* document 15850/08 MI 453 SAN 274 AGRILEG 206 ECO 161.

⁹ "The Council shall act by a simple majority regarding procedural matters and for the adoption of its Rules of Procedure."

12. It is suggested that the procedure for the appointment of the representatives be as follows:
- the members of the Permanent Representatives Committee will be given an opportunity to express their views on the various candidates if they wish;
 - the Permanent Representatives Committee will vote by secret ballot, Member States' delegations each having one vote;
 - each Member State delegation is entitled to vote for two candidates representing patients, one candidate representing doctors and one candidate representing veterinarians. Delegations also have the option of abstaining from voting for any candidate;
 - candidates' names will appear in alphabetical order on each ballot paper;
 - if at the first count there is a simple majority (at least fourteen votes) in favour of:
 - = one or two candidates representing patients, the Committee will recommend that the Council appoint this candidate / these candidates;
 - = one candidate representing doctors, the Committee will recommend that the Council appoint this candidate;
 - = one candidate representing veterinarians, the Committee will recommend that the Council appoint this candidate;
 - concerning those posts for which there is not a simple majority (at least fourteen votes) at the first count, further ballots will be held until two candidates for patients, one candidate for doctors and one candidate for veterinarians have received fourteen votes or more. In each ballot the candidate receiving the lowest number of votes shall be eliminated.

C. TERM OF OFFICE

13. In accordance with Article 65(4) of Regulation (EC) 726/2004 the term of office shall be three years. It is suggested that the Council leave it to the Management Board to set the date on which the term of office of the persons appointed will start.

D. PUBLICATION OF THE COUNCIL DECISION

14. It is suggested that the Council Decision making this appointment be published in the Official Journal of the European Union, as is normally the case regarding such appointments.

Conclusion

The Permanent Representatives Committee is invited to

- **approve the arrangements described in point 12 above;**
- **in accordance with point 12, establish which of the candidates representing patients, doctors and veterinarians have the strongest support;**
- **verify that a qualified majority can agree to recommending to the Council to appoint to the posts as member of the Management Board of the EMA the candidates selected in accordance with point 12;**
- **agree that the starting date of the three-year term of office of the persons to be appointed as members of the Management Board of the EMA will be set by the Management Board;**

and to

- **invite the Council to decide at a forthcoming meeting:**
 - = **to appoint the persons thus recommended (a draft Decision for this purpose appears in Annex I hereto);**
 - = **to have the appointing Decision published in the Official Journal of the European Union.**

COUNCIL DECISION

of

**appointing four members of the Management Board
of the European Medicines Agency
(EMA)**

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to 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 Agency¹, and in particular Article 65(1) and Article 65(4) thereof,

Having regard to the list of candidates drawn up by the Commission on 16 September 2008,

Having regard to the Opinion of the European Parliament,

HAS DECIDED AS FOLLOWS:

¹ OJ L 136, 30.4.2004, p. 1.

Article 1

....., born in on,, born in on,, born in on, and, born in on shall be hereby appointed members of the Management Board of the European Medicines Agency (EMA) for a period of three years.

Article 2

The date on which the three-year period referred to in Article 1 will commence shall be determined by the Management Board of the European Medicines Agency (EMA).

Done at Brussels,

For the Council

The President

EMA MANAGEMENT BOARD – CANDIDATE LIST OF CIVIL SOCIETY REPRESENTATIVES**Doctors' organisations:**

Standing Committee of European Doctors	Rolf-Dieter Ludwig
United European Gastroenterology Federation	Miguel A. Gassull¹
	Walter Reinisch¹

Veterinarians' organisations:

Federation of Veterinarians of Europe	Christophe Hugnet
	Peter Glynn Harleth Jones

Patients' organisations:

Thalassaemia International Federation	Androulla Eleftheriou
International Diabetes Federation	Wim Wientjes
The European Consumer Organisation	Monique Goyens
Europa Uomo	Erik Briers
European Patients Forum	Mike O'Donovan²
European AIDS Treatment Group	Nikolaos Dedes

¹ Please note that this candidate was erroneously listed among candidates proposed by patients' organisation in the Commission Decision (document 11966/12). The Commission will issue a corrected Decision where he is listed as a candidate for representing doctors' organisations.

² The Council Secretariat has informally been informed that this candidate has decided to withdraw.