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AGRILEG 66

NOTE

From: General Secretariat of the Council
To: Permanent Representatives Committee

No. Cion doc.: 7380/19 PHARM 12 SAN 141 MI 244 AGRILEG 52 + ADD 1

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 726/2004¹ provides that the Council, in consultation with the European Parliament, shall appoint two representatives of patients' organisations ("the patients' representatives"), one representative of doctors' organisations ("the doctors' representative") and one representative of veterinarians' organisations ("the veterinarians' representative") as members of the Management Board of the European Medicines Agency (EMA)². Those four representatives shall be selected from a list drawn up by the Commission.
2. The term of office for the current four representatives will end on 14 June 2019.

¹ Regulation (EC) No 726/2004 of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency. (OJ L 136, 30.4.2004, p. 1.)

² The Management Board consists of one representative of each Member State, two representatives of the Commission, two representatives of the European Parliament and the four representatives of patients', doctors' and veterinarians' organisations.

3. On 11 March 2019, the Council received a Commission Decision³, which contains a list⁴ of candidates from which the four representatives referred to above shall be selected. The list contains only one candidate each for the posts⁵ as doctors' representative and as veterinarians' representative and eight candidates for the posts as patients' representatives⁶. The Commission has also provided the *curricula vitae* of the candidates.
4. On 23 April 2019, the Council received an official letter⁷, in which the European Parliament lists the candidates it recommends for appointment.
5. On 24 April 2019, the Council Secretariat sent a letter to the Deputy Permanent Representatives and to the Health Attachés, containing in Annex the list of candidates together with the *curricula vitae* of the candidates.

B. PROCEDURE FOR APPOINTING THE FOUR REPRESENTATIVES

6. Given that the EMA Management Board shall include one representative of doctors' organisations and one representative of veterinarians' organisations, the Council must appoint the proposed candidates for the post as doctors' representative and the post as veterinarians' representative.
7. With regard to the selection of the candidates for the posts as patients' representatives it is proposed to follow the procedure used for previous appointments⁸ to the EMA Management Board. That procedure is outlined in Annex II.
8. The Permanent representatives Committee is invited to agree by a **simple majority** of its members (at least fifteen votes), in accordance with Article 240(3) of the Treaty on the functioning of the European Union ("TFEU")⁹, to use the procedure outlined in Annex II.

³ Commission document C(2019) 621 final. Council document 7380/19 PHARM 12 SAN 141 MI 244 AGRILEG 52 + ADD 1.

⁴ This list is also set out in Annex I to this Note.

⁵ The persons in question are the current doctors' and veterinarians' representatives.

⁶ One of those candidates, Mr. Yann LE CAM, is currently a patients' representative.

⁷ Document 7703/19 PHARM 16 SAN 161 MI 278 AGRILEG 67.

⁸ See *e.g.* document 7503/1/16 REV 1 PHARM 14 SAN 109 MI 183 AGRILEG 33.

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

9. After selecting the candidates to be appointed patients' representatives, the Committee is invited to verify that a qualified majority of its members (Article 238(3)(b)¹⁰ TFEU) could support a decision to recommend to the Council to appoint all four selected candidates.
10. The Committee is also invited to agree to recommend to the Council that the term of office¹¹ of the persons now appointed will start on 15 June 2019, which is before the next meeting of the EMA Management Board.
11. Finally, the Committee is invited to agree to recommend to the Council that the Decision making these four appointments be published in the Official Journal of the European Union, as is normally the case regarding such appointments.

C. CONCLUSION

The Permanent Representatives Committee is invited to :

- **select the two candidates proposed by the Commission for the posts as doctors' and veterinarians' representatives;**
- **agree by simple majority to select two candidates for the posts as patients' representatives following the procedure set out in Annex II;**
- **verify that a qualified majority can agree to recommend to the Council to appoint the four candidates thus selected as the patients' representatives, the doctors' representative and the veterinarians' representative in the EMA Management Board;**
- **agree that the starting date of the three-year term of office of the four representatives will be 15 June 2019;**

and to :

- **suggest to the Council to decide at a forthcoming meeting:**
 - = **to appoint the persons thus recommended for a three-year period from 15 June 2019 (a draft Decision for this purpose appears in Annex III hereto);**
 - = **to have the Decision published in the Official Journal of the European Union.**

¹⁰ "..., where the Council does not act on a proposal from the Commission or from the High Representative of the Union for Foreign Affairs and Security Policy, the qualified majority shall be defined as at least 72 % of the members of the Council representing the participating Member States, comprising at least 65 % of the population of these States." It follows that a qualified majority consists of at least 21 Member States.

¹¹ In accordance with Article 65(4) of Regulation (EC) No 726/2004 the term of office shall be three years.

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

| | |
|--|---------------------------|
| Standing Committee of European Doctors (CPME) | WOLF-DIETER Ludwig |
|--|---------------------------|

Veterinarians' organisations:

| | |
|--|------------------------|
| Federation of Veterinarians of Europe (FVE) | DE BRIYNE Nancy |
|--|------------------------|

Patients' organisations:

| | |
|---|----------------------------|
| European Patients' Forum (EPF) | GRECO Marco |
| European Organisation for Rare Diseases (EURORDIS) | LE CAM Yann |
| European Public Health Alliance (EPHA) | NATSIS Ioannis |
| Cystic Fibrosis Europe (CF Europe) | NOORDHOEK Jacquelin |
| European Institute of Women's Health (EIWH) | SUNDSETH Hildrun |
| AGE Platform Europe | PARENT Anne-Sophie |
| Amyotrophic Lateral Sclerosis Liga Belgium (ALS) | REVIERS Evy |
| Danish Consumer Council | JENSEN Sine |

Selection of the patients' representatives

1. It is suggested that the procedure for the selection of the patients' representatives be as follows:
 - the Permanent Representatives Committee will vote by secret ballot¹² in order to select the two patients' representatives, each Member State delegation having two votes. Each delegation can:
 - = vote for two candidates;
 - = vote for one candidate, and consequently abstain from using its second vote;
 - = abstain from voting for any candidate;
 - if at the first count there is a simple majority (at least fifteen votes) in favour of exactly two candidates for becoming patients' representatives, the Committee will recommend that the Council appoint these candidates;
 - if it is not possible to select two¹³ candidates for becoming patients' representatives based on the first count, further ballots will be held until all but two candidates have been eliminated pursuant to point 2.

2. In order to decide which candidates shall be retained for the next ballot, or selected, the following rules apply:
 - a) in each ballot (including the first one) the candidate(s) receiving the lowest number of votes¹⁴ shall be eliminated;
 - b) once all but three candidates have been eliminated, the two candidates that received the highest number of votes shall be selected, even if that number of votes is lower than fifteen;
 - c) if, when all but three candidates have been eliminated, those three candidates have received an equal number of votes, the Chair shall choose two of them for appointment.

¹² Candidates' names will appear in alphabetical order on each ballot paper.

¹³ This situation includes the cases where no candidate, one candidate or three candidates receive at least fifteen votes.

¹⁴ All candidates that receive zero votes are eliminated. In addition, the candidate(s) that receive(s) the lowest non-zero number of votes is/are eliminated.

DRAFT¹⁵
COUNCIL DECISION (EU) 2019/...
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 on the Functioning of the European Union,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹⁶, and in particular Article 65(1) and (4) thereof,

Whereas:

- (1) On 30 January 2019, the Commission, acting in accordance with Article 65(1) of Regulation (EC) No 726/2004, adopted a list of candidates, representatives of patients' organisations, doctors' organisations and veterinarians' organisations, to be appointed to the Management Board of the European Medicines Agency.
- (2) The European Parliament considered that list of candidates and submitted its views thereon to the Council on 16 April 2019.

HAS ADOPTED THIS DECISION:

¹⁵ Subject to legal-linguistic finalisation.

¹⁶ OJ L 136, 30.4.2004, p. 1.

Article 1

The following are hereby appointed members of the Management Board of the European Medicines Agency for a three-year period from 15 June 2019:

| PATIENTS' ORGANISATIONS | DOCTORS' ORGANISATIONS | VETERINARIANS' ORGANISATIONS |
|----------------------------|---------------------------|---------------------------------|
| Mr/Ms ... Mr/Ms... | Mr/Ms ... | Mr/Ms ... |

Article 2

This Decision shall enter into force on the date of its adoption.

Done at ...,

For the Council
The President
