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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
No. Cion doc.:	6108/16 PHARM 9 SAN 51 MI 80 AGRILEG 16
Subject:	Appointment of four members of the Management Board of the European Medicines Agency (EMA) - <i>Procedure</i>

In this revised document Point 14 and the Conclusion have been changed since it is proposed that the Council decide on the date when the term of office begins. Annex I is updated to reflect suggestions for better legal drafting.

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 27 January 2016, 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 letter 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 letter², 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 candidates³ 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 candidates⁴ 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 ten⁵ candidates for the post of Management Board member representing patients. The European Parliament is expected to retain two of these candidates, in order of preference, for consideration by the Council.

¹ Commission document C(2016) 2112 final. Council document 6108/16 PHARM 9 SAN 51 MI 80 AGRILEG 16.

² Document 7695/16 PHARM 15 SAN 124 MI 202 AGRILEG 39.

³ See Annex II.

⁴ See Annex II.

⁵ See Annex II.

B. PROCEDURE

8. Under Article 16(3) of the Treaty on European Union⁶, 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 ten 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 points 12 and 13⁷. 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 Union⁸, be adopted by a **simple majority** (at least fifteen votes) of its members.
11. After selecting the candidates to be appointed following the procedure in points 12 and 13, the Committee could verify that a qualified majority of its members (Article 238(2)⁹ of the Treaty on the Functioning of the European Union¹⁰) could support a decision to recommend to the Council to appoint those candidates.

⁶ "The Council shall act by a qualified majority except where the Treaties provide otherwise."

⁷ That procedure was used in previous appointments of members of the EMA management board. See *e.g.* document 15798/12 PHARM 79 SAN 267 MI 692 AGRILEG 163.

⁸ "The Council shall act by a simple majority regarding procedural matters and for the adoption of its Rules of Procedure."

⁹ "By way of derogation from Article 16(4) of the Treaty on European Union, as from 1 November 2014 and subject to the provisions laid down in the Protocol on transitional provisions, 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 Member States comprising at least 65 % of the population of the Union."

¹⁰ A qualified majority thus consists of at least 21 Member States. This is without prejudice to the possible application of the transitional provisions of Article 3 of Protocol no. 36, if requested by a Member State. (In which case at least 260 votes in favour representing at least two thirds of the Members of the Council are required.)

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 fifteen votes) in favour of:
 - = two¹¹ candidates representing patients, the Committee will recommend that the Council appoint 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;
 - if it is not possible to select two candidates representing patients, one candidate representing doctors and one candidate representing veterinarians based on the first count, further ballots will be held until two candidates for patients, one candidate for doctors and one candidate for veterinarians¹² have been selected pursuant to point 13.

¹¹ If no candidate, one candidate or three candidates receive at least fifteen votes, the procedure in point 13 shall apply.

¹² The consequence of rules a), b) and c) in point 13 is that the candidate for veterinarians will be selected based on the votes cast in the first ballot.

13. 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 receiving the lowest number of votes¹³ shall be eliminated;
 - b) once all but two (for patients all but three) candidates have been eliminated, the candidate (for patients 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 two (for patients all but three) candidates have been eliminated the remaining candidates received an equal number of votes, the Chair shall choose one (for patients two) of them for appointment.

C. TERM OF OFFICE

14. In accordance with Article 65(4) of Regulation (EC) 726/2004 the term of office shall be three years. The term of office for the representatives appointed in 2013 has ended. It is suggested that the Council decide that the term of office of the persons now appointed will start on 15 June 2016, which is before the next meeting of the Management Board.

D. PUBLICATION OF THE COUNCIL DECISION

15. 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.

¹³ If several candidates receive the same (lowest) number of votes they are all eliminated.

Conclusion

The Permanent Representatives Committee is invited to

- **approve the arrangements described in points 12 and 13 above;**
- **in accordance with points 12 and 13, 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 points 12 and 13;**
- **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 15 June 2016;**

and to

- **invite the Council to decide at a forthcoming meeting:**
 - = **to appoint the persons thus recommended for a three-year period from 15 June 2016 (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.**

DRAFT¹⁴
COUNCIL DECISION (EU) 2016/...

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 Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency¹⁵, and in particular Article 65(1) and (4) thereof,

Whereas:

- (1) On 27 January 2016, the Commission, acting in accordance with Article 65(1) of Regulation (EC) No 726/2004, presented 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 21 April.

HAS ADOPTED THIS DECISION:

¹⁴ Subject to legal-linguistic finalisation.

¹⁵ 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 2016:

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

**EMA MANAGEMENT BOARD - CANDIDATE LIST OF CIVIL SOCIETY
REPRESENTATIVES**

Doctors' organisations:

Standing Committee of European Doctors (CPME)	André Herchuelz
	Wolf-Dieter Ludwig
European Association of Urology (EAU)	Hendrik Van Poppel

Veterinarians' organisations:

Federation of Veterinarians of Europe (FVE)	Nancy De Briyne
	Hans-Joachim Götz

Patients' organisations:

Myeloma Euronet Romania member of Myeloma Patients Europe	Viorica Cursaru
International Patient Organisation for Primary Immunodeficiencies (IPOPI)	Jose Drabwell
European Organisation for Rare Diseases (EURORDIS)	Yann Le Cam
International Diabetes Federation (IDF)	João Manuel Nabais
Rett Syndrome Europe (RSE)	Gerard Nguyen Duc Long
Bureau Européen des Unions de Consommateurs (BEUC – European Consumer Organisation)	Ilaria Passarani
European Patients' Forum (EPF)	Susanna Palkonen
Federazione Italiana Epilessie (FIE)	Francesca Sofia
European Cancer Patient Coalition (ECPC)	Rafal Swierzewski
International Diabetes Federation (IDF)	Wilhelmus Henricus Johannes Maria Wientjens