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'A' ITEM NOTE

From: General Secretariat of the Council
To: Council

No. prev. doc.: 7702/19 PHARM 15 SAN 160 MI 277 AGRILEG 66

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 2004¹ laying down Union 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' organisations and one representative of veterinarians' organisations as members of the Management Board of the European Medicines Agency (EMA).
2. On 11 March 2019, the Council received a Commission Decision², setting out a list of candidates relating to the nomination of four members of the EMA Management Board for a period of three years commencing in 2019.

¹ OJ L 136, 30.4.2004, p. 1-33.

² Commission document C(2019) 621 final. Council document 7380/19 PHARM 12 SAN 141 MI 244 AGRILEG 52 + ADD 1.

3. On 23 April 2019, the Council received an official letter³, in which the European Parliament listed the candidates it recommended for appointment.
4. On 6 May 2019, the Council Secretariat issued a document⁴ explaining the procedure for appointment of the four members of the Management Board.
5. On 24 May 2019, the Permanent Representatives Committee selected two representatives of patients' organisations, one representative of doctors' organisations and one representative of veterinarians' organisations for appointment as members of the EMA Management Board. The Committee unanimously agreed to recommend to the Council to appoint those representatives.
6. The Committee further agreed to recommend that their term of office would start on 15 June 2019 and that the Decision should be published in the Official Journal of the European Union.

Consequently, the Council is invited:

- **to adopt the Decision set out in document 9059/19⁵**
and
- **to have that Decision published in the Official Journal of the European Union.**

³ Document 7703/19 PHARM 16 SAN 161 MI 278 AGRILEG 67.

⁴ Document 7702/19 PHARM 15 SAN 160 MI 277 AGRILEG 66

⁵ Document as finalised by the legal-linguists.