

Brussels, 25.2.2019 C(2019) 1449 final

COMMISSION DECISION

of 25.2.2019

appointing members and alternates of the Pharmacovigilance Risk Assessment Committee to represent healthcare professionals and patients' organisations

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THE EUROPEAN COMMISSION.

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 Agency¹, and in particular Article 61a(1) thereof,

Whereas:

- (1) Article 61a(1) of Regulation (EC) No 726/2004 requires that the Commission appoints representatives of healthcare professionals and patient organisations to the European Medicines Agency Pharmacovigilance Risk Assessment Committee.
- (2) In accordance with Article 61a(1) of Regulation (EC) No 726/2004, a public call for expression of interest has been undertaken by the Commission. The European Parliament has been consulted on the results of the evaluation including the reserve list, for the applications, received in the framework of this call for expression of interest.
- (3) The members and alternates of the Committee shall be appointed for a period of three years starting on 1 March 2019, which may be prolonged once.
- (4) Where a member or alternate appointed by this decision is no longer capable of contributing efficiently to the work of the Committee, or resigns, the Commission may replace this member from the reserve list, for the remaining duration of the member's or alternate's mandate.

HAS DECIDED AS FOLLOWS:

Article 1

- 1. The following are hereby appointed members and alternates of the Pharmacovigilance Risk Assessment Committee to represent healthcare professionals for a term of three years from 1 March 2019:
 - Member: John Raymond ANDERSON,
 - Alternate: Ylva BÖTTIGER.
- 2. The following are hereby appointed members and alternates of the Committee to represent patient organisations for a term of three years from 1 March 2019:
 - Member: Cathalijne VAN DOORNE,
 - Alternate: Virginie HIVERT.

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OJ L 136, 30.4.2004, p. 1.

Article 2

- 1. The following are hereby placed on a reserve list of members and alternates of the Pharmacovigilance Risk Assessment Committee to represent healthcare professionals:
 - Roberto FRONTINI,
 - Donald SINGER.
- 2. The following are hereby placed on a reserve list of members and alternates of the Pharmacovigilance Risk Assessment Committee to represent patient organisations:
 - Matija CEVC,
 - Rafal SWIERZEWSKI,
 - Declan NOONE.

Article 3

This Decision shall take effect on the day of its adoption.

Done at Brussels, 25.2.2019

For the Commission Vytenis ANDRIUKAITIS Member of the Commission