

27 February 2015
EMA/MB/40714/2015 Adopted
Management Board meeting of 19 March 2015

Management Board liaison process for PRAC composition

Liaison after the first 3 years of PRAC

Background

Article 61a of Regulation (EC) No 726/2004 states:

1. The Pharmacovigilance Risk Assessment Committee shall be composed of the following:

(a) one member and one alternate member appointed by each Member State, in accordance with paragraph 3 of this Article;

(b) six members appointed by the Commission, with a view to ensuring that the relevant expertise is available within the Committee, including clinical pharmacology and pharmacoepidemiology, on the basis of a public call for expressions of interest;

(c) one member and one alternate member appointed by the Commission, on the basis of a public call for expressions of interest, after consulting the European Parliament, in order to represent healthcare professionals; ...

3. The members and alternate members of the Pharmacovigilance Risk Assessment Committee shall be appointed on the basis of their relevant expertise in pharmacovigilance matters and risk assessment of medicinal products for human use, in order to guarantee the highest levels of specialist qualifications and a broad spectrum of relevant expertise. For this purpose, Member States shall liaise with the Management Board and the Commission in order to ensure that the final composition of the Committee covers the scientific areas relevant to its tasks.

4. The members and alternate members of the Pharmacovigilance Risk Assessment Committee shall be appointed for a term of 3 years, which may be prolonged once and thereafter renewed following the procedures referred to in paragraph 1. ...

The Management Board adopted in March 2012 a liaison process at each 3 year interval ('Pharmacovigilance and Risk Assessment Committee (PRAC): Consultation procedure on final composition and replacement of members/alternates' (EMA/MB/139702/2012)).

This document describes the process for the liaison after the first 3 years of PRAC in 2015 and thereafter.

Liaison process for the June 2015 Management Board meeting

- Following the invitation to the Member States in January 2015 to prolong the mandate of the PRAC members and alternates or to nominate a new PRAC member or alternate, the EMA secretariat provides the Management Board with:
 - an overview of the current composition of the PRAC with an indication for each member and alternate if it regards a new or prolonged mandate and with the expertise of each member and alternate;
 - a gap analysis on the expertise within the PRAC;
 - a recommendation on criteria for experience and expertise for PRAC members and alternates to be provided to the nominating authorities for consideration when the Agency invites the nomination for a PRAC member or alternate.
- The European Commission informs the Management Board on the prolongation of the mandate for the six independent experts or the nomination of one or more new members with a view to enhance the relevant expertise in the Committee.
- The Management Board reviews and discusses the list of PRAC members and alternates and their expertise to identify gaps in expertise, while noting new and prolonged mandates.
- The Management Board gives an opinion whether the current PRAC committee has sufficient relevant expertise and
 - recommends the appointment of the PRAC members and alternates as nominated by Member States, and
 - issues recommendations whether further expertise is needed in certain areas.

The above process will be applied for the liaison with the Management Board at each 3 year interval.

Activities until the next liaison process with the Management Board in 2018

- The EMA secretariat maintains an overview of the current composition of the PRAC with an indication for each member and alternate if it regards a new, prolonged or renewed mandate, and with the expertise of each member and alternate. At the end of the mandate of a PRAC member or alternate or when the position becomes vacant, the Agency invites the Member State to either:
 - prolong the mandate of a PRAC member or alternate (membership can only be prolonged once);
 - renew the mandate of a PRAC member or alternate (whose mandate has already been prolonged);
 - nominate a new member or alternate to the PRAC.
- With each invitation, the EMA secretariat provides the Member States with the overview of the expertise of PRAC members and alternates, the Management Board recommendations on further expertise needed in certain areas and the recommendation for criteria for experience and expertise of PRAC members and alternates.
- The EMA secretariat reviews the available expertise within the PRAC as appropriate. In case a major discrepancy in expertise with the PRAC is noted, the EMA secretariat brings this to the attention of the Management Board.

- When appropriate, the Management Board may provide an updated recommendation on what further expertise is needed in certain areas to be provided to the Member States when invited to nominate a PRAC member or alternate.

The above activities will be performed during each 3 year period.