EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 March 2012
EMA/MB/139702/2012 Adopted

Pharmacovigilance and Risk Assessment Committee (PRAC): Consultation procedure on final composition and replacement of members/alternates

Management Board meeting 22 March 2012

Background note

Regulation (EC) No 726/2004 as amended by Regulation (EU) No 1235/2010 obliges Member States, appointing members and alternates to the Pharmacovigilance Risk Assessment Committee (PRAC), to liaise with the Management Board and the European Commission on the final composition of the Committee.

Extracts from the regulation, 14. Article 61a (the full text can be found here http://ec.europa.eu/health/files/eudralex/vol-1/reg_2010_1235/reg_2010_1235_en.pdf):

"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 Committee shall elect its Chairman from among its members for a term of 3 years, which may be prolonged once."

Matters for consideration

While the Management Board has a consultative role in the appointment of members to the CHMP and CVMP, the legislation for the PRAC is different in the following points:

- Member States shall liaise with the Board **and the Commission** in order to ensure that the **final** composition of the Committee covers the scientific areas relevant to its tasks; and

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
An agency of the European Union

- Members and alternates shall be appointed for a term of 3 years, **which may be prolonged once** and **thereafter renewed following the same procedure as tor the original appointment**.

The procedures suggested below, have been drafted to take these differences into account. The Management Board is invited to consider these, specifically how the liaison element of the process could be implemented in practice.

Liaison process for the first PRAC composition

1.1. The Agency invites Member States to nominate candidates as members and alternates to the PRAC (Article 61a 1.(a)) and submits the list of nominees to the Management Board. (Completed)

1.2. The EMA secretariat reviews the list of nominees to identify gaps in expertise and informs the European Commission. (Completed)

1.3. The European Commission appoints six members with a view to enhance the relevant expertise in the Committee (Article 61a 1.(b)). The European Commission also appoints two members and alternates to represent healthcare professionals and patient organisations. (In progress)

1.4. At its meeting on 7 June 2012, the Management Board discusses the list of nominees.

The Management Board gives an opinion whether the Committee has sufficient relevant expertise and
- recommends appointment of members and alternates as nominated by Member States; and
- issues recommendations whether further expertise is needed in certain areas.

1.5. This recommendation is sent to Member States' competent authorities and published as part of the meeting minutes. National authorities are asked to take this recommendation into account when making changes to nominations.

1.6. Committee members and alternates serve a mandate of 3 years.

Liaison process at each 3 year interval

2.1. The Agency invites Member States to either (Article 61a 4.)
- **prolong** the mandate of a PRAC member/alternate (membership can only be prolonged once)
- **renew** the mandate of a PRAC member/alternate (whose mandate has already been prolonged once)
- **nominate a new** member/alternate to the PRAC

Most recent recommendations referred to in point 3.1 below are included.

The EMA secretariat submits the full list of nominations to the Management Board and European Commission

2.2. The Management Board and the European Commission review the list of **new** and **renewed** nominations to identify gaps in expertise, while noting members/alternates whose mandates have been prolonged.

2.3. The European Commission appoints six members with a view to enhance the relevant expertise in the Committee (Article 61a 1.(b)).

2.4. The Management Board discusses the list of new/renewed nominees, noting prolonged

memberships.

The Management Board gives an opinion whether the Committee has sufficient relevant expertise and
- recommends appointment of members and alternates as nominated by Member States, or
- issues recommendations whether further expertise is needed in certain areas

2.5. This recommendation is sent to Member States' competent authorities and published as part of the meeting minutes. National authorities are asked to take this recommendation into account when making changes to nominations.

Activities during the 3 year term

3.1. When appropriate the Management Board may provide an updated recommendation on what further expertise is needed in certain areas (the required competence may change depending on the types of issues the committee will be dealing with, and on the availability of expertise over time).

3.2. This information is sent to Member States' competent authorities asking them to take the recommendations into account when nominating members within the three year period.