22 June 2017
EMA/483011/2015
Inspections, Human Medicines Pharmacovigilance and Committees

Recommendation on criteria for experience and expertise of PDCO members and alternates

Legislation

Article 4 (1) of Regulation (EC) No 1901/2006 states that the Paediatric Committee shall be composed of the following members:

(a) five members, with their alternates, of the Committee for Medicinal Products for Human Use, having been appointed to that Committee in accordance with Article 61(1) of Regulation (EC) No 726/2004. These five members with their alternates shall be appointed to the Paediatric Committee by the Committee for Medicinal Products for Human Use;

(b) one member and one alternate appointed by each Member State whose national competent authority is not represented through the members appointed by the Committee for Medicinal Products for Human Use.

For the purposes of points (a) and (b), Member States shall cooperate, under the coordination of the Executive Director of the Agency, in order to ensure that the final composition of the Paediatric Committee, including members and alternates, covers the scientific areas relevant to paediatric medicinal products, and including at least: pharmaceutical development, paediatric medicine, general practitioners, paediatric pharmacy, paediatric pharmacology, paediatric research, pharmacovigilance, ethics and public health.

Recommendation

The following recommendation on criteria for experience and expertise is made to nominating authorities in the Member States for consideration when the Agency invites them to nominate a new PDCO member and alternate. CHMP members and their alternates are invited to bear this recommendation in mind when considering putting themselves forward for a CHMP-PDCO joint membership:

- **Academic expertise** in the relevant scientific area, such as:

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- Internationally recognised academic qualification(s)/accreditation(s) (e.g. degrees, diplomas, post graduate qualifications (e.g. PhD), professional affiliations etc.) in life sciences or physical sciences (medicine, pharmacy, chemistry, biology, …)
- Delivering scientific expert views/opinions to National/European/International scientific bodies.

- **Direct working experience**, after obtaining the academic qualification, in the relevant scientific area, in a **national competent authority, industry and/or academia/clinical practice** (university, hospital, research facility, private practise, etc.). Relevant experience will depend on the core activities of the Committee but could be expected to include experience in one or more of the following areas:
  - Clinical expertise in one or more therapeutic areas (either as a medical doctor or as a hospital pharmacist)
  - Clinical co-ordinator/investigator in clinical trials
  - Member of Data Safety Monitoring Board or Scientific Advisory Board and/or experience of working in or with ethics approval committees
  - Pre-clinical research and expertise (e.g. in toxicology, pharmacology, animal models)
  - Clinical research (e.g. clinical trials, epidemiological studies)
  - Research in the relevant "quality" areas, relating to the research and development of medicinal products (e.g. molecular biology, gene technology)
  - Formulation, manufacture and control of medicinal products
  - Pharmacovigilance and risk management
  - Advisory experience (leading to knowledge of regulatory requirements) in committees'/ scientific bodies' activities (e.g. member of Working Party or SAG, nominated by EMA or NCA for involvement in EMA activities, experience in providing scientific advice for central and/or national MAs, involvement in WHO, EDQM, FDA activities)
  - Experience in the review of dossiers, preparation and provision of assessments reports for central and/or national MAAs, experience in peer review of Assessment Reports/List of Questions
  - Targeted publications in recognised and peer-reviewed scientific journals and/or peer reviewing activities for scientific journals

- **Members and alternates nominated to the PDCO** would be expected to have **expertise** in one of the areas of expertise required by the legislation and/or in one of the additional areas of expertise identified by the Committee:
  - Scientific areas relevant to paediatric medicinal products *as per legal requirement*:
    - pharmaceutical development
    - paediatric medicine
    - general practitioners
    - paediatric pharmacy
    - paediatric pharmacology
    - paediatric research

- pharmacovigilance
- ethics
- public health

– *Additional areas* of expertise identified by the Committee – therapeutic areas
  - cardiovascular diseases
  - dermatology
  - diagnostic
  - endocrinology – metabolism
  - gastroenterology
  - gynaecology – fertility
  - haematology – hemostaseology
  - hepatology
  - immunology – rheumatology – transplantation
  - infectious diseases
  - neurology
  - oncology
  - ophthalmology
  - oto-rhino-laryngology
  - pain
  - pneumology – allergology
  - psychiatry
  - uro-nephrology
  - vaccines

– *Additional areas* of expertise identified by the Committee – scientific and other areas
  - adolescent medicines
  - cell therapy – gene therapy – tissue engineering
  - clinical pharmacology, modelling and simulation
  - extrapolation
  - neonatology
  - non-clinical development of medicinal products, including expertise in juvenile animal studies to support neonatal and paediatric studies
  - paediatric pharmacovigilance
  - pharmacometrics

- quality of medicines, such as expertise on pharmaceutical forms, formulations and pharmaceutical development
- rare diseases and orphan medicinal products
- statistics in medicine and clinical trials

Whilst a minimum period for post graduate experience is not defined, please note for information, that the length of experience of CHMP and PRAC members and alternates in June 2015 ranged from 2 to 40 years and in 2 out of 3 cases the member had a greater number of years of relevant experience compared to the alternate.