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Inspections, Human Medicines Pharmacovigilance and Committees

Recommendation on criteria for experience and expertise of COMP members

Legislation

Article 4 (3) of Regulation (EC) No 141/2000 states that the Committee for Orphan Medicinal Products shall consist of one member nominated by each Member State, three members nominated by the European Commission to represent patients' organisations and three members nominated by the European Commission on the basis of a recommendation from the European Medicines Agency. The Regulation does not specify the expertise required for COMP members as is the case for the other Scientific Committees.

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 COMP member. The Agency will bear them in mind when recommending nominations to the European Commission:

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

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- 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 nominated to the COMP** would be expected to have **expertise** in one of the following areas of expertise identified by the Committee:
  - Cardiovascular diseases
  - Clinical genetics
  - Dermatology
  - Endocrinology
  - Haematology
  - Hepatology
  - Immunology
  - Infectious diseases
  - Internal medicine
  - Metabolic diseases
  - Musculoskeletal disorders
  - Neurology
  - Oncology
  - Ophthalmology
  - Pulmonology
  - Psychiatry

- Surgery / Transplantation
- Urology
- Clinical experience with one or more rare diseases in any therapeutic area
- Advanced Therapies
- Antidotes
- Clinical pharmacology
- Epidemiology
- Health related quality of life
- Molecular biology
- Paediatrics
- Pharmaceutical development
- Pre-clinical activities (e.g. pharmacologytoxicology, pharmacokinetics, pharmacodynamics)
- Public health
- Radiopharmaceuticals
- Statistics

Whilst a minimum period for such 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.