EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management and Committee Support

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

The following recommendation on criteria for experience and expertise is made to nominating authorities and committees for consideration when the Agency invites them to nominate a new CHMP member and alternate:

- **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)
  - 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)
  - Scientific research (e.g. in epidemiological studies, animal 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

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- Advisory experience (leading to knowledge of regulatory requirements) in committees'/ scientific bodies' activities. For example: 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 etc.)
- Experience in the review of dossiers, preparation and provision of assessments reports for central and/or national MAAs / experience in peer review of CHMP Assessment Reports/List of Questions
- Targeted publications in recognised and peer-reviewed scientific journals and / peer reviewing activities for scientific journals.

- **Members and alternates nominated to the CHMP** would be expected to have **expertise** in at least one of the following areas – Quality, Non-Clinical, Clinical (general or covering therapeutic areas from the mandatory scope of the centralised procedure), with optional expertise in other therapeutic areas:
  - Quality
    - Synthetic chemicals
    - Biotech and biological
  - Non-clinical
    - Pharmacology and toxicology
  - Clinical (general)
    - Clinical pharmacology
    - Clinical pharmacokinetics
    - Statistics with experience from clinical trials methodology
    - Pharmacovigilance with expertise in epidemiology
    - Paediatrics
  - Clinical (mandatory scope)
    - Oncology
    - Diabetes and metabolism
    - Neurology
    - AIDS
    - Auto-immune diseases and other auto-immune dysfunctions
    - Viral diseases
    - Advanced therapies (gene, cell, tissue engineered)
  - Other therapeutic areas identified by the CHMP
    - Blood products
    - Cardiovascular diseases
    - Dermatology

- Gastroenterology
- Ophthalmology
- Psychiatry
- Respiratory diseases
- Rheumatology and musculoskeletal diseases
- Vaccinology

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.