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Procedure Management and Committee Support

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

Legislation

Article 16h (2) h of Directive 2001/83/EC states that each Member State shall appoint one member and one alternate to the Committee for Herbal Medicinal Products. Members and alternates shall be chosen for their role and experience in the evaluation of herbal medicinal products. The HMPC may co-opt a maximum of five additional members chosen on the basis of their specific scientific competence. With a view to the co-opting of such members, the HMPC shall identify the specific complementary scientific competence of the additional member(s). Co-opted members shall be chosen among experts nominated by Member States or the Agency.

Recommendation

The following recommendation on criteria for experience and expertise is made to nominating authorities for consideration when the Agency invites them to nominate a new HMPC member and alternate and to HMPC members and alternates when considering the nomination of co-opted members:

- **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, 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 MAAs, 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 HMPC** would be expected to have **expertise** in at least one of the following areas: Quality, Non-clinical, Clinical – general, Clinical – therapeutic areas (focus OTC), and with optional expertise in other HMPC relevant areas:
 - Quality
 - Analytical chemistry
 - Phytochemistry
 - Development pharmaceuticals
 - Quality control (including stability)
 - Botany, taxonomy, plant physiology
 - Biological assays and biochemistry (including protein purification/analysis)
 - Non-clinical
 - Toxicology (in vitro/in vivo)
 - Pharmacology (in vitro/in vivo)
 - Pharmacodynamics
 - Pharmacokinetics
 - Clinical – general
 - Clinical pharmacology (including safety pharmacology and pharmacokinetics)
 - Clinical trials methodology and statistics

- Pharmacovigilance (including epidemiology, signal detection, risk assessment and management)
- Paediatrics
- Geriatrics
- Medical practice (i.e. medical doctor)
- Other medical practice
- Clinical - therapeutic areas (focus OTC)
 - Alimentary track and metabolism (constipation, gastrointestinal disorder, loss of appetite, mouth and throat disorders)
 - Respiratory system (cough and cold, mouth and throat disorders)
 - Ophthalmology (eye discomfort)
 - Nervous system (mental stress and mood disorder, fatigue and weakness, pain and inflammation, sleep disorders and insomnia)
 - Dermatology (skin disorders and minor wounds, pain and inflammation)
 - Urology and gynaecology/obstetrics (urinary tract and gynaecology disorders)
 - Cardiovascular diseases and circulatory disorders (venous circulatory disorders)
- Other HMPC relevant areas
 - Consumer protection and public health
 - European traditional phytotherapy (classic)
 - Anthroposophic medicine and other specific European traditional medicines
 - TCM, Ayurvedic and other Asian traditional medicines
 - African traditional medicines
 - American traditional medicines
 - Other areas as: Inspections/GMP/GLP/GCP, GACP and plant cultivation, Microbiology, Food safety and food legislation, Medical devices, Biologicals, biotechnology, gene therapy, cell therapy, tissue engineering

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.

Nominating authorities in the Member States are expected to provide HMPC members and alternates sufficient possibilities to engage in HMPC work.