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Inspections, Human Medicines Pharmacovigilance and Committees

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

Legislation

Article 21 (1) of Regulation (EC) No 1394/2007 states that the Committee for Advanced Therapies (CAT) shall be composed of the following members:

(a) five members or co-opted members of the Committee for Medicinal Products for Human Use from five Member States, with alternates either proposed by their respective Member State or, in the case of co-opted members of the Committee for Medicinal Products for Human Use, identified by the latter on the advice of the corresponding co-opted member. These five members with their alternates shall be appointed 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 among the members and alternates appointed by the Committee for Medicinal Products for Human Use.

Article 21 (2) states that all members of the CAT shall be chosen for their scientific qualification or experience in respect of advanced therapy medicinal products. For the purposes of paragraph 1(b), the Member States shall cooperate, under the coordination of the Executive Director of the Agency, in order to ensure that the final composition of the Committee for Advanced Therapies provides appropriate and balanced coverage of the scientific areas relevant to advanced therapies, including medical devices, tissue engineering, gene therapy, cell therapy, biotechnology, surgery, pharmacovigilance, risk management and ethics. At least two members and two alternates of the Committee for Advanced Therapies shall have scientific expertise in medical devices.

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 CAT member and alternate. CHMP members and their alternates are invited to bear this recommendation in mind when considering putting themselves forward for a CHMP-CAT joint membership:

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Send a question via our website www.ema.europa.eu/contact

- **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 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 CAT** would be expected to have **expertise** in one of the areas of expertise relevant to advanced therapy medicinal products required by the legislation and/or in one of the additional areas of expertise identified by the Committee:
  - Areas of expertise relevant to advanced therapy medicinal products *as per legal requirement*:
    - cell therapy
    - gene therapy
    - tissue engineering
    - biotechnology
    - medical devices

- surgery
- pharmacovigilance
- risk management
- ethics

– *Additional areas* of expertise identified by the Committee

- Pre-clinical experience with advanced therapy medicinal products
- Clinical experience with advanced therapy medicinal products
- Biostatistics
- Clinical trial methodology and clinical trials

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.