

Patients and healthcare professionals in EMA's scientific committees

Commission call on patient and healthcare representatives for PRAC/CAT

Patients/Consumer Working Party and Healthcare professionals WG
24 September 2012, Florian Schmidt, DG SANCO

The role of patients and healthcare professionals in scientific committees

- *Patients and healthcare professionals are now present in many of the scientific committees of the Agency*
- *Recognition of the need for "real-life" experience*
- *Advocacy of patients' interests*
- *Advocacy of healthcare professionals' interests*
- *Supplementing scientific expertise*
- *Yes, we are asking a lot*

Pharmacovigilance Risk Assessment Committee - PRAC

- *New Committee established in the framework of the new pharmacovigilance legislation*
- *Key role in the evaluation of pharmacovigilance signals*
- *Gives recommendations to other EMA committees on regulatory follow-up and all pharmacovigilance questions*
- *Consists of Members representing national competent authorities, independent scientific experts and one patient representative (+ alternate) and one healthcare professional representative (+ alternate)*

Committee for Advanced Therapies - CAT

- *Established in 2008*
- *Responsible for preparing a draft opinion on the quality, safety and efficacy for each advanced therapy medicinal product*
- *Consulted on other questions which require specific expertise in advanced therapies*
- *Consists of CHMP members, members representing national competent authorities, two members (and two alternates) representing clinicians, two members (and two alternates) representing patients' associations*

Why a new call?

- *In September 2011 the Commission already published a call searching for 'civil society' representatives for PRAC and CAT*
- *European Parliament disappointed by the low number of applications asked the Commission to re-launch the call*
- *New call published in July 2012*

Recurrent problem – Low number of applications

- *Scientific committee – specific profile requested*
- *Workload*
- *Committee/professional life balance*
- *Unpaid activity*
- *Number of associations – Number of committees and working groups*

Whom we are looking for - Patients

Patient organisation representative: One main task is patient advocacy so to ensure that patient needs as a whole are taken into account in the deliberations of the Committee. Public safety communication on individual medicinal products should for example consider specific patient requirements. The candidate should be a member of a patient organisation. Although a medical background is not a requirement, a broad knowledge of medical and legislative issues related to the approval and use of medicines is recommended and will be needed to effectively contribute to the scientific discussions of the Committee. A broad understanding of pharmaceutical safety issues in specific disease areas and beyond and related regulatory aspects would be an advantage.

Whom we are looking for – Healthcare professionals

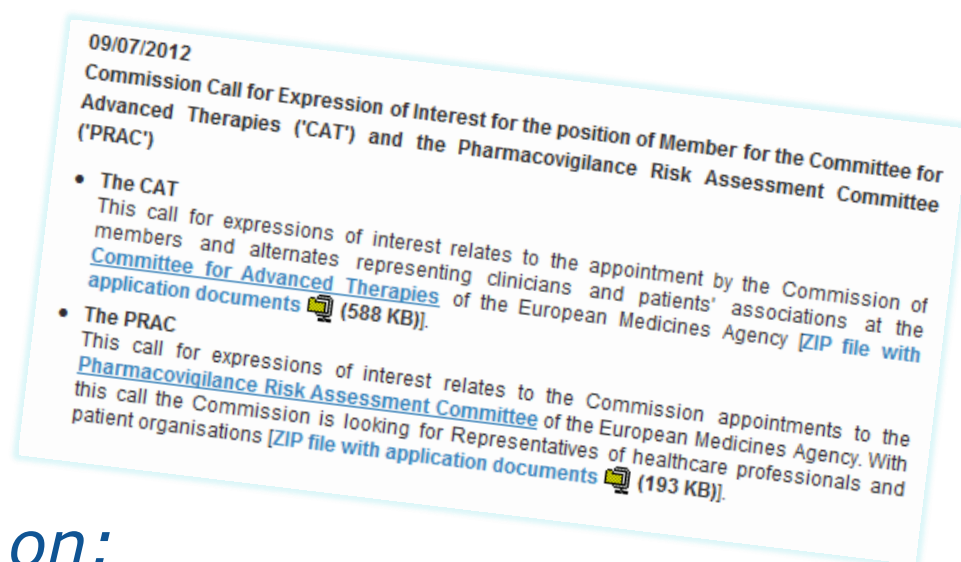
Healthcare professional representative: This member should ensure that the needs of practitioners, clinicians, pharmacists or other healthcare professionals on the ground and real-life implications are taken into account, when addressing safety issues, particularly in consideration of the fact that some of the outcome documents produced by the Committee will be addressing the healthcare professional directly. The candidate should be a member of a healthcare professional organisation and have a good understanding of pharmacovigilance related matters. Proven experience in liaison and communication with healthcare professionals will be an advantage.

Appointment process

- *Call for the expression of interest*
- *Pre-screening regarding conflicts of interest*
- *Meeting of a selection panel of the Commission*
- *Establishing a short list of most suitable applicants by order of merit, including a proposal for selection*
- *Consultation of the European Parliament on the proposal*
- *Finalising the appointment decision*
- *Adoption and publication of the Commission decision appointing the new members*

Application documents

- *a letter of motivation (signed)*
- *the completed application form (signed)*
- *the completed form on declaration of interests (signed)*
- *a curriculum vitae*



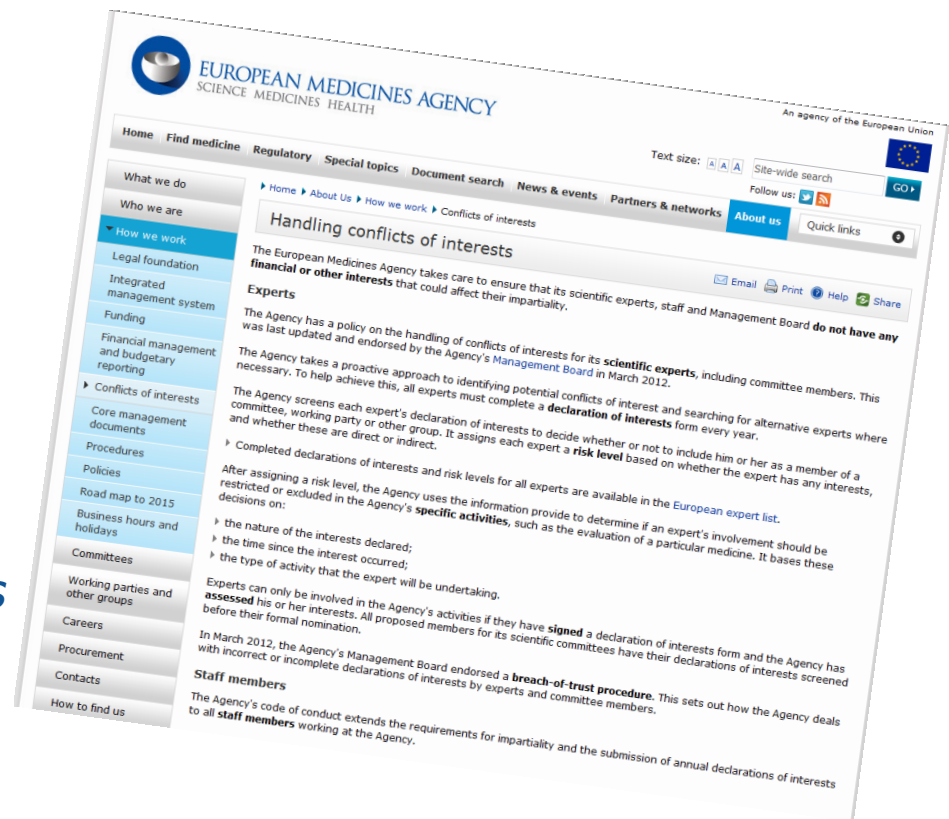
All documents available on:

http://ec.europa.eu/health/human-use/index_en.htm [news and updates]

Deadline for submitting applications: 1 October

Final word on conflict of interest

- *Important for the credibility and legality of EMA's work output*
- *Correct and thoroughly completed forms should be provided*
- *Direct interest(s) will lead to the non-consideration of the application*
- *EMA published guidance on its policy*



We count on you!

Please provide us with applications so to allow that the final selection of members and alternates is based on a sufficiently large pool of candidates