EUROPEAN COMMISSION

Directorate-General for Health & Consumers

Commission Call for Expression of Interest for the position of Member of the Pharmacovigilance Risk Assessment Committee

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Call for Expression of Interest

- 30/09/2011
  http://ec.europa.eu/health/documents/new_en.htm
- Pharmacovigilance Risk Assessment Committee (PRAC)
  - representatives of healthcare professionals and patient organisations
  - independent scientific experts
- *EMA Management Board, CAT, COMP in parallel*
- Submission of applications till 1 December 2011

PRAC

- Regulation (EC) No 726/2004
- a new scientific committee from July 2012
- a key function in the evaluation of the safety of medicines and risk minimisation measures at EU level
- detection, assessment, minimisation and communication relating to the risk of adverse reactions

- Recommendations
  - any Union-wide post-authorisation assessment based on pharmacovigilance data
  - on risk management systems and monitoring their effectiveness

Representatives of patients organisations and healthcare professionals

- Article 61a (1) of Regulation (EC) No 726/2004
- member + alternate “to represent patient organisations”,
- member + alternate “to represent healthcare professionals”
- the European Parliament to be consulted

- specific focus on the target group they represent (advocacy)
- input based on the real-life experience of those affected by a disease and its current therapeutic environment
- to contribute by assessing the real-life implications of regulatory decisions

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Representatives of patients organisations and healthcare professionals

- applications for representatives of HCP and PO preferably to be submitted by the organisations they represent
- provide a presentation of the organisation(s) represented, including the organisation's legitimacy (i.e. statutes registered in a MS of the EEA) mission and objectives, capability to represent patients or healthcare professionals, whether the governing body is elected, how accountability an transparency of funding and activities are ensured.

Independent experts

- 6 independent scientific expert members “to ensure that the relevant expertise is available within the Committee, including clinical pharmacology and pharmacoepidemiology”, Article 61a (1) of Regulation (EC) No 726/2004

- key expertise for performing PRAC tasks consists of risk identification, risk assessment (including clinical pharmacology and pharmacoepidemiology), risk management, risk minimisation, risk communication as well as knowledge on pharmacovigilance systems.

- to contribute to high level discussions

Workload and procedure

- appointed “on the basis of their relevant expertise in pharmacovigilance matters and risk assessment of medicinal products for human use, in order to guarantee the highest levels of specialist qualifications and a broad spectrum of relevant expertise“
- for a period of three years, which may be prolonged once and thereafter renewed

Workload and procedure

- maximum 4 days meetings
- preparatory work
- electronic methods for the management and exchange of documents
- English
- travel, accommodation and subsistence costs – reimbursement rules, EMA

Declaration of interests

- shall not have financial or other interests in the pharmaceutical industry which could affect their impartiality
- act in the public interest and in an independent manner
- an annual declaration of their financial interests
- declarations at each meeting of any specific interests which might be considered prejudicial to their independence in relation to the items on the agenda

- applicants are also requested to submit a declaration of interest form

Assessment criteria HCP and POs

- representation at the EU level
- individuals have competencies and experience relevant to the tasks of the PRAC
- ability and experience in representing organisations, and the characteristics of the organisations represented (i.e. representing the interests and perspectives of those directly affected by regulatory decisions)

Assessment criteria independent experts

- relevant expertise in view of the mandate of the PRAC, highest level of specialist qualifications and a broad spectrum of relevant expertise
- individuals have competencies and experience relevant to the tasks

Application procedure

- a letter of motivation (signed)
- the completed application form (signed)
- the completed form on declaration of interests (signed)
- a CV
- if appropriate, supporting documents may be annexed

- download for on-screen completion - print

Application procedure

- All candidates shall be informed about the outcome
- The Commission will ensure that candidates' personal data are processed as required by Regulation (EC) No 45/2001 of the EP and of the Council on the protection of individuals with regard to the processing of personal data by the Union institutions and bodies and on the free movement of such data (confidentiality, security)
  http://ec.europa.eu/health/human-use/index_en.htm

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Thank you