



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance Working Party (PhVWP): Co-opted members with PhEPI experience

Call for expression of interest

Henry Fitt
Section Head, Co-ordination and Networking, PhV-RM

An agency of the European Union





What is the PhVWP?

- The PhVWP provides advice on the safety of medicines authorised in the EU and the investigation of ADRs to enable effective identification, assessment and management of risk, at any phase in the product life cycle.
- PhVWP provides recommendations for regulatory action to its stakeholders, i.e. the CHMP, the Agency and National Competent Authorities.
- The advice should be in a precise and operational format and in accordance with timeframes set by such stakeholders and/or Community legislation.



Mandate, Objectives and Rules of procedure

Please visit the following link:

http://www.emea.europa.eu/htms/general/contacts/CHMP/CHMP_PhVWP.html



Roles and responsibilities

- Co-opted PhVWP members should contribute to the key responsibilities of the PhVWP, in particular:
 - Evaluation of potential signals arising from spontaneous reporting, including those identified from the EV database and all other sources, including epidemiological databases, studies and published literature
 - Provision of advice on confirmation and quantification of risk and on regulatory options
 - Risk management by advising on RM plans
 - Monitoring regulatory action and the outcome of such actions



Rules of participation

- PhVWP membership implies a commitment to participate actively in its work and attend its meetings regularly [2.5 days/month]
- A co-opted PhVWP member may not be replaced when (s)he is unable to attend the meeting
- The European Medicines Agency will reimburse travel and accommodation expenses for the co-opted PhVWP members



How to apply?

- Letter of motivation
- CV

Apply by sending the above documents to:

ENCePP_Secretariat@ema.europa.eu

Deadline for Expression of Interest is close of business on 11 January 2010.