EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Nomination of members to the Pharmacovigilance Risk Assessment Committee (PRAC)

Fourth Stakeholder Forum on the implementation of the new Pharmacovigilance legislation
27th February 2012, London

Presented by: Sheila Kennedy

New Pharmacovigilance Risk Assessment Committee PRAC

The Mandate shall cover…

All aspects of the risk management of the use of medicinal products including the **detection, assessment, minimisation and communication relating to the risk** of adverse reactions, having due regard to the therapeutic effect of the medicinal product, the design and evaluation of post-authorisation safety studies and pharmacovigilance audit

PRAC membership

Appointed by each Member State:

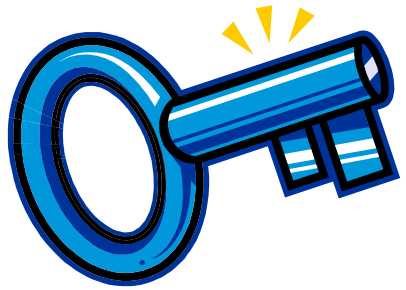
- 1 member + alternate from each MS + 1 member and alternate from EEA countries (non voting members)

Appointed by the European Commission following a public call for expressions of interest:

- 1 patient organisations[1] rep + alternate
- 1 healthcare professionals[1] rep + alternate
- 6 members to ensure relevant expertise available

[1] *Criteria for involvement in EMA activities*

PRAC membership – key points



- A Member State may delegate its tasks in the Pharmacovigilance Risk Assessment Committee to another Member State
- Members appointed for 3-year term, which may be prolonged once and thereafter renewed
- Chairman – 3-year term, which may be prolonged once
- Member States shall liaise with the Management Board and the Commission in order to ensure that the final composition of the Committee covers the scientific areas relevant to its tasks

Pharmacovigilance Risk Assessment Committee

Expertise

The members and alternate members of the Pharmacovigilance Risk Assessment Committee shall be 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**

Core areas of Expertise

- Risk identification: e.g signal detection and management
- Risk assessment
- Risk and therapeutic effect assessment (benefit risk assessment)
  - Clinical pharmacology and therapeutics
  - Epidemiology and Medical statistics
  - Pharmacoepidemiology
- Risk communication
- Risk management
- Risk minimisation and evaluation of impact of measures
- Pharmacovigilance systems, audits and inspections

Complementary areas of expertise

- Pharmacovigilance in selected populations: (paediatric, elderly)
- Vaccines pharmacovigilance
- Drug Safety in pregnancy and lactation
- Medication errors leading to adverse reactions
- Misuse and abuse of medicinal products
- Patient safety / clinical practice
- Drug utilisation studies
- Pharmacovigilance and quality defects
- Pharmacogenetic and safety of medicines
- Pharmacovigilance of biologic medicines (including cell and gene therapy)
- Safety of medicines for selected systems/organ classes (– e.g. expertise in ADRs in Dermatological, Hepatic, Cardiovascular, Oncological, CNS areas)

Nomination process

Sept. 30th 2011:	European Commission Call for Expression of Interest in PRAC membership – Independent Scientific Experts, Patients and Health Care Professionals – *deadline December 1st 2011*
Dec. 5th 2011	Request to EC Permanent Representatives for Member State nominations – *requested by Jan. 15th 2012.*
Situation to Date: (MS nominations)	Nominations received from 21 Member States to date (6 outstanding).

Next steps

- Preparation of overview of expertise (Member State nominations) - *ongoing*
- Appointment of members (and alternates as appropriate) by European Commission
- Liaison with Management Board and Commission on composition of Committee – *June 2012*

1st meeting of PRAC – July 2012

Time for questions