

# Patients' involvement in the PRAC

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Workshop on the patient-voice in the  
evaluation of medicines

Joint meeting PCWP/HCPWP

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# Content

- Introduction to and short history of patient involvement in pharmacovigilance activities
- Composition of the PRAC
- The role of the patient representative at the PRAC
- Some early observations
- The alternate position

# Directive 2010/84/EU and Regulation (EU) no 1235/2010

- Pharmacovigilance rules are necessary for the protection of public health in order to prevent, detect and assess adverse reactions to medicinal products placed on the Union market, **as the full safety profile of medicinal products can only be known after they have been placed on the market.**

# Involvement in Pharmacovigilance activities

- 2009: trial, observer and alternate at three meetings of the PhVWP
- 2010 – 2012: Observer and alternate at the PhVWP
- From April 2013: Member and alternate at the PRAC
- Involved representatives: David Haerry, Greetje Goossens, Christina Cabrita, Marco Greco and Albert van der Zeijden

# Members of the PRAC

- Chair
- 28 representatives of member states
- 1 representative of Iceland and 1 of Norway
- 6 independent scientific experts nominated by the EC
- 1 representative of p.o's and 1 of health care professionals nominated by the EC after consultation of the EP
- For all members there is an alternate

# The role of the patients' representative

- Same as all other members, with special expertise
- Add patients' experiences and perspectives to the expertise of regulators and other experts
- Not the watchdog of patients organisations
- Contribute to the opinion building on benefit risk assessments of medicines, content of texts like DHPC's, PL's etc.

# Observations

- Tremendous amount of documents, all electronically available
- Long working days
- Patients well introduced, but a need for personalised assistance
- Cooperation of representative and observer enriches the input of both

# Current position of the alternate

- Either only the member or the alternate are reimbursed
- Currently no reimbursement means no attendance
- Position of a patients representative is different from the representative of a NCA
- EMA Management Board has to consider to reimburse the member and the alternate