EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Workshop on patient's voice in the evaluation of medicines

PCWP and HCPWP joint meeting, 26 September 2013

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The medicines landscape

Nature of medicines is changing - shift to biologicals and personalised medicines

Healthcare changing – patient centred, outcome focussed

Healthcare data systems offering new capabilities for capturing real world benefit and risk

Context for today's workshop

Regulation is changing:

- benefit risk throughout life-cycle
- quantitative benefit risk models
- earlier access
- adaptive licensing
- transparency and openness
- greater inclusiveness

Why patient voice important?

Patients have key role in evaluation of:

- What benefit is meaningful
- What risk is acceptable
- Whether balance of benefits and risk is favourable and in what population
- How evidence of benefit risk is communicated to support decision-making
- Feasibility and acceptability of risk minimisation

Key challenges

- In moving from ad hoc to systematic involvement throughout medicines life-cycle, how to ensure that integrating the patient's voice has maximal value?

- How to adapt regulatory procedures and processes to best support this integration?

- How to demonstrate the added value of integrating the patient's voice in regulation?