EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Involvement of patients in PRAC benefit-risk

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Outline of presentation

What was experience of patient observers in Pharmacovigilance Working Party?

Why is patient perspective vitally important to work of the Pharmacovigilance Risk Assessment Committee?

How can patient involvement in PRAC benefit risk be optimised?

Pharmacovigilance Working Party Pilot conclusions -2009

1. The patient and medicines user: final arbiter of acceptable risk
2. Patient view important to put safety information into context (clinical practice, public health)
3. Identify topics requiring additional PCO consultation; act as link to other experts
4. Facilitate implementation of new legislation

Patient Observers

International Alliance of Patients' Organizations

EMP
EUROPEAN MYELOMA PLATFORM
patients for patients

beuc
The European Consumers' Organisation

Albert van der Zeijden
Chairman of IAPO

Greetje Goossens
EMP counsellor

Cristina Cabrita BEUC

Key learning from PhVWP experience

- Perspective of patient observers not necessarily same as scientific/technical experts
- Provides an extra dimension which adds value and builds a more rounded evaluation
- Value of patient contribution throughout entire range of issues, not only drafting of patient information

Aims of Pharmacovigilance legislation

- Clarity on roles and responsibilities
- Proactive safety monitoring
- Robust and timely decision-making leading to consistent action on safety issues for nationally and centralised authorised products
- Best use of resources – avoiding duplication of effort
- High levels of transparency
- Greater inclusiveness for patients and healthcare professionals

Mandate of the Pharmacovigilance Risk Assessment Committee

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

Membership of PRAC

Appointed by each Member State:

1 member + alternate

27 + EEA countries non voting members

Appointed by European Commission:

6 members - relevant expertise including clinical pharmacology and pharmacoepidemiology

1 member/alternate representing patient organisations

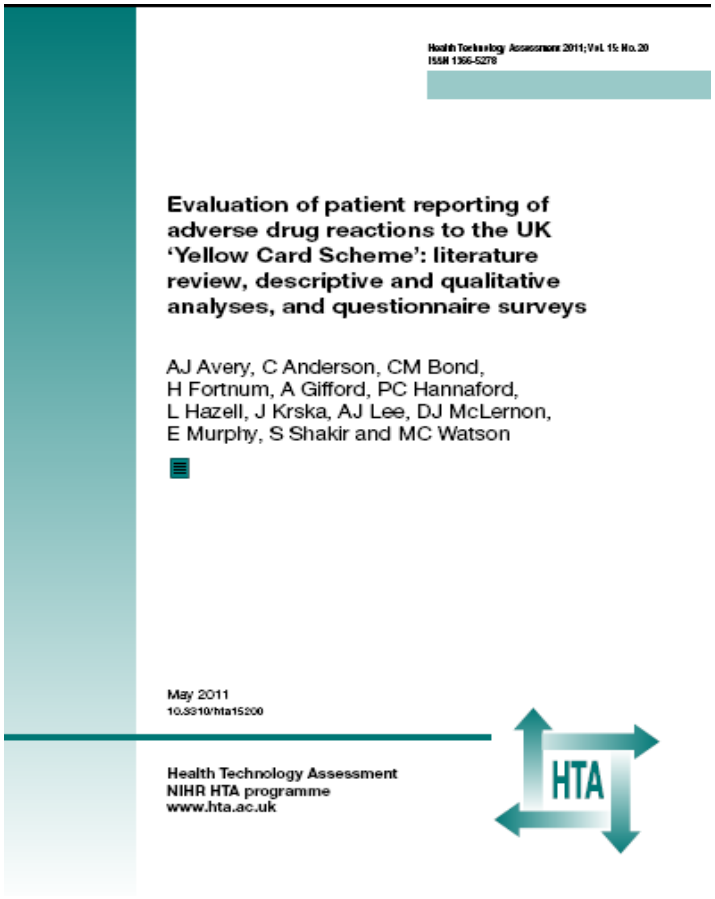
1 member/alternate representing healthcare professionals

Why patient involvement at PRAC?

Patients will 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

Evidence from Patient Reporting



- Similar proportion of "serious" adverse drug reactions
- More detailed description of adverse drug reaction
- More signals when combined HCP and patient reports
- Different patterns of drugs and reactions reported by patients

Avery et al 2011

Example: Tolcapone (Tasmar)

I have just heard from my doctor's surgery that the new drug, tolcapone, which I have just been started on has been withdrawn from the market

I have been amazed at the almost instantaneous improvement in my Parkinson's disease since starting this drug. I can now eat food with no difficulty, and can sit down and eat with the rest of the family instead of having to wait for hours until I drifted into a state when I could eat. I have been able to have a shower, taking only a few minutes instead of an hour or more, and can shave, walk briskly and easily outdoors alone and have even rearranged my daughter's hen-house for her. I can sleep restfully and have cooked a meal for my daughter.

The idea of stopping this drug now that I have regained so much of my normal activity is almost unimaginable and fills me with dread. I cannot see that it could be in any way justified. I am quite willing to take full responsibility for taking the drug, and should I experience any side effects, even a fatal reaction neither I nor my family would hold anyone responsible.

Patient representatives -added value

- Input into implementation of new pharmacovigilance systems
- Promotion of adverse reaction reporting
- Safety issues where public hearings will be appropriate
- When to involve specific patient organisations

Example – choice of Black Symbol

For medicines subject to Additional Monitoring

All new active substances and biologicals, including biosimilars; obligation to conduct a safety study, or to conditions or restrictions (optional)

Views of patients/consumers were key to selection of symbol by PRAC

PRAC Referrals Sept-Nov 2012

Codeine (analgesia)	- toxicity in children
Diclofenac	- cardiovascular risk
Short-Acting Beta-Agonists	- in obstetric use
Hydroxyethyl starch solutions	- morbidity/mortality
Almitrine	- neuropathy
Diacerein	- hepatotoxicity

What issues would be appropriate for a public hearing?

How can patient involvement in PRAC be optimised?

Clarity on scope of role

Tailored induction

Support and briefing

Monitoring and feedback

Conclusions

Patient representatives are integral to the new Pharmacovigilance Risk Assessment Committee, and key to achieving greater inclusiveness of European drug safety systems

Patients' contribution to a robust benefit-risk evaluation is vital

Now that PRAC is established, preparing for the optimal involvement of patient representatives is a priority