EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance in the elderly: Conclusions

EMA workshop: Ensuring safe and effective medicines for an ageing population

23 March 2012

An agency of the European Union

Conclusions

- What we have discussed
- How to further strengthen pharmacovigilance
- Opportunities for change

Conclusions: what have we discussed

Denis O'Mahony: clinical experience and optimal prescribing / delivery of care

Ulf Bergman: critical importance of pharmacokinetics and dynamics in the elderly

Dolores Montero: practical experience of a regulator

Georgy Genov: EudraVigilance and signal detection

Stella Blackburn: Role of risk management – proactivity and planning

Michael Richardson: industry considerations for pharmacovigilance

Conclusions: how to strengthen pharmacovigilance 1

Risk management – based on the risk profile – plan to fill knowledge gaps through post-authorisation studies; targeted risk minimisation

Collection of data – optimise all possible data sources – facilitate reporting of suspected side effects, patient reporting; drug utilisation; electronic health records

Detecting new safety issues – huge potential to better use spontaneously reported adverse reactions: drug-drug and drug-disease interactions; focus on off-label use, medication errors, event clusters (e.g. falls dizziness);

Conclusions: how to strengthen pharmacovigilance 2

Evaluation of safety issues – always consider the elderly

Benefit risk evaluation – dedicated consideration of elderly population; specific patient values placed on benefits and risks

Regulatory action – consider targeted action

Communications – meet the information needs of the elderly; support decision-making; target communication and risk minimisation

Conclusions: opportunities for change

Excellent public health protection and promotion requires:

- Science; legislation; resources

Harness the opportunities:

- regulatory sciences – methods for collecting data, signal detection, bias and confounding in observational studies, novel clinical trial design, biomarkers
- new pharmacovigilance legislation – current consultations; dedicated new guidance; new tools (e.g. patient reporting)
- Resources: Research funding (IMI, Framework Programme etc); Accessing data; funding studies; expert staff; involving patients

Conclusion

We can further strengthen the protection and promotion of the health of the elderly, through enhanced pharmacovigilance.

..and in partnership with stakeholder…..we will