EMEA Viewpoint on the Innovative Medicines Initiative

Pharmacovigilance

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Content of presentation

- The Innovative Medicines Initiative
  - observations
  - proposals
- The EMEA viewpoint
  - where are the IMI observations and proposals discussed ?
  - status of discussions

Observations

- A wealth of epidemiological data on drug exposure and outcomes is available in the EU, but
  - no central repository of such data
  - different data sources do not communicate
  - data cannot be combined
- Systems and networks for pharmacovigilance are used for regulation, not for research
- Methods of Pv have remained unchanged for two decades
- Risk minimisation methods are not yet available for testing
- Effectiveness of risk communication is put into question

Proposals

1. Optimisation of data resources and strengthening of evidence base

2. Development and strengthening of methodologies and networks

3. Development of novel methods of risk prediction and benefit:risk assessment

4. Training and education

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Where are IMI proposals and observations discussed ?

- EMEA/CHMP-Think Tank group on Innovative drug development
  - series of meetings with individual pharmacutical companies (n=14) and academic groups/learned societies (n=4) during 2006
  - Goal: to identify bottlenecks in the development of medicinal products and discuss new methods and procedures
  - Draft report in December 2006

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- International Conference for Harmonisation- ICH E2F
  - ICH: scientific and technical discussions related to safety, quality and efficacy of medicines, between regulatory authorities and industry from Europe, United-States and Japan as full members, and others (WHO, Canada, Switzerland, etc.) as observers.
  - ICH E2F is a new guideline on Development Safety Update Report (DSUR) for the periodic review and analysis of safety information from investigational programs (e.g. clinical trials)
  - Finalisation expected in November 2008

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- EMEA project "European Network of Centres for Pharmacoepidemiology and Pharmacovigilance" (ENCePP)

- Other EMEA projects
  - Eudravigilance Expert Working Group
  - Review & Learning project (with CHMP and PhVWP)

    retrospective survey of RMPs submitted to EMEA; assessment of quality, implementation and effectiveness; entering phase II
  - EMEA/CHMP Working Group with Patient Organisations
  - Evaluation of benefit-risk assessment methods and criteria

Proposals (1)

1. Optimisation of data resources and strengthening of evidence base

Short-term

- inventory of EU data sources
- network of database owners – dialogue on quality standards
- EU academic network of pharmacoepidemiology

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ENCePP

What has EMEA done?

- Inventory of 55 academic & research centres covering 18 MSs and >10 major disease areas
- Inventory of 4 specific paediatric centres
- Inventory of industry experience with centres

What are we working on?

- Network Structure & Working Model (other relevant networks ?)
- Role of EMEA in network structure
- Funding of network structure and actual studies
- Meeting with centres to agree on network model
- Inventory of databases and patient registries

Proposals (1)

1. Optimisation of data resources and strengthening of evidence base

Long-term

- electronic patient record
- data pooling and integration (CT, Sp, PE, utilisation data)
- standardisation of medical and medicinal product data
- EU data warehouse

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Integration of pre- and post-authorisation safety data

- Integration of DSUR and PSUR highly desirable to provide comprehensive view of product safety throughout lifecycle. However, many technicalities need to be solved

- RCT data need to be included in EV

EU datawarehouse

- Eudravigilance Datawarehouse in validation phase
- Signal detection tools designed by EV Expert group

Electronic patient record

- national basis

Proposals (2)

2. Development and strengthening of methodologies and networks

- signal detection and data mining
- intensive monitoring of medicines based on clinic, hospital, community or regional centre approach
- data sources and methods for risk assessment for specialised medicines (e.g. biological, vaccines) or special populations
- methodologies for risk minimisation and risk communication, incl. evaluation of effectiveness
- pharmacovigilance-specific ontology

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- Access to EV signal detection tools for MAHs
  - use of product-related information in context
  - strengthening of scientific base for signal detection
- ENCePP to provide network of centres of excellence for specialised areas, including access to databases
- Methods for risk assessment and signal detection for specific classes, e.g. pandemic influenza vaccines
- Need for proper evaluation of effectiveness of risk management plans and outcome results

Review & Learning project should also consider

- provision of competence in risk management
- availability of expertise at the levels of CAs and MAHs

Proposals (3)

3. Development of novel methods of risk prediction and benefit:risk assessment

- new technologies and methods to better predict safety profile
- new methods of benefit:risk analysis (incl. decision analysis tool)

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- Academic project on evaluation of benefit-risk assessment methods and criteria
  - survey and analysis of explicit and implicit criteria for benefit-risk evaluation by CHMP
  - analysis of interactions between risk management and benefit- risk evaluation
  - potential role of quantitative methods of benefit-risk assessment
  - structure of benefit-risk evaluation

Proposals (3)

4. Training and education

- identification of training needs for HCPs and development of training programmes
- development and testing of training and education programmes for patients, especially on benefit:risk of medicines

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EMEA/CHMP Working Group with Patient Organisations

Improvements need to be achieved in the areas of:

- transparency and dissemination of information
- product information
- pharmacovigilance
- interaction between EMEA/CHMP and Patients Organisations

Thank you !