EUROPEAN COMMISSION

Directorate-General for Health & Consumers

New Challenges for the EMA:

Implementation of the 'pharmaceutical package' and beyond

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EUROPEAN COMMISSION

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New Challenges for the EMA

- Introduction – the Agency
- Short-term legal challenges: the “pharma package”
- Long term assessment: Roadmap, HMA strategy, Evaluation of the Agency

Introduction (I) - the Agency

- “Network Agency”
- Strong Member States involvement/based on Member States’ experience
- A system set up with the objective of science-based policy making
- Composed of scientific committees and a secretariat

Introduction (II) - the Committees

- Most committee members represent and appointed by Member States, all Member States have a seat
- Some committee members are chosen to represent organisations or because of their experience
- Committee members are independent
- Rapporteurs and co-rapporteurs to produce reports for peer-review
- Secretariat to assist on all tasks

Introduction (III) - Resources

- Human resources from Member States and organisations provided voluntarily
- Mission expenditure reimbursed for all
- Secretariat resources paid by Agency budget
- Ca. 80% of financial resources of Agency paid by fees, 20% by EU-budget
- Majority of rapporteurships and co-rapporteurships result in payments from Agency to Member States' agencies

Pharma package (I) - Pharmacovigilance

- Eudravigilance database
- Webportal on safety information
- Pharmacovigilance Risk Assessment Committee
  - PSUR assessment
  - Involvement in PASS

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- Webportal on medicinal products

Pharma package (II) – falsified medicines

- EudraGMP/EudraGDP
- Support for 3rd country list of API manufacturers

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- Support for setting up guidelines on excipients and ‚brokering' of medicines
- Distance-selling in e-commerce?

Pharma package (III) – 'Information to patients'

- Many critical voices
- Commissioner has announced to re-assess the proposal to give it a stronger patient perspective

Clinical trials

- EMAs role at present very limited
- Commitment to revise the Directive – legislative proposal is planned for autumn 2011
- Impact assessment ongoing

Strategic developments

- HMA Strategy – under review
- EMA Roadmap – in public consultation
- Evaluation by the Commission – finalised and published

EMA- Evaluation (I)

- Required by legislation
- Conducted by consultancy firm
- Under lead of the Commission and steering group with Agency participation
- Report covers many aspects beyond « architecture »
- Follow-up conference in June 2010

EMA – evaluation (II)

Increase in roles and functions since 1995

- Orphan legislation (2000)
- Review of pharmaceutical law (2004)
- Paediatric legislation (2006)
- Advanced therapies (2007)
- Revised variations (2009)

Enlargements of 2004 and 2007

EMA – evaluation (III)

- Conclusions confirm successful work of EMA
- However:
  - Committee architecture complex
  - Workload for ‚main committees' problematic
  - ‚Burden sharing' for Member States is a challenge for the future

Conclusion

- EMA indispensable contributor to ensuring European regulation
- The concept of a „Network – agency“ has proven a success, nevertheless, major challenges are ahead of EMA, in particular in view of the ever-expanding responsabilities

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Thank you