



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session 2: European Medicines Network Coordinating role of the Agency within the network- clarifying roles and responsibilities

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EMA



Content

- A bit of law
- A bit of Ernst and Young
- Some current activities
- Looking to the future



Regulation (EC) No 726/2004

- Article 56:

“Secretariat, which shall provide technical, scientific and administrative support for the committees and ensure appropriate coordination between them”

- Article 57:

“The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety and efficacy of medicinal products for human and veterinary use which is referred to it in accordance with the provisions of Community legislation relating to medicinal products. the following tasks:



A bit of Ernst and Young

A few quotes

- “The EMA secretariat strongly contributes in the effectiveness of the system”
- “The EMA Secretariat has proved to be a learning organisation identifying very early topics.....”
- “Stakeholders generally recognize that EMA continuously strives to improve both its timelines and its procedures”
- “At international level, all stakeholders recognise the quality of EMA contribution...”



Some current activities

(Not a catalogue)

- Hub of the EU Medicines Network
- Administration
- Information technology
- Data Management
- Information and communications
- Scientific process
- Scientific networks
- Public Health Initiatives
- International activities



Future – some guiding principles

- To protect and promote public health, stimulate innovation and access to medicines:
 - Strive for excellence in science, administration, IT, data management and communications
 - EMA Secretariat, EMA Committees and NCAs working as a team
 - Identify and embrace frontiers in science, regulation and society
 - Research: identify the questions, improve the methods, build the capacity, when appropriate conduct the research



Ernst and Young Recommendations

- Ten recommendations for the secretariat



Future

Recommendation 7, 8 and 9: Identifying experts

Work as a team to identifying the best expertise, to

- Meet the challenges of new science
- Meet the challenges of new product technologies
- Meet the challenges of new information technologies
- Meet the challenges of data management and data analysis
- Meet the challenges of a changing society



Future

Recommendation 13: The EMA Secretariat should strengthen its ability to monitor the consistency of EMA outputs

Team for:

- integrated working
- scientific excellence and consistency
- regulatory excellence and consistency
- quality assurance

Research on outcome of regulation on health



Future

Recommendation 14: EMA Secretariat should put in place specific support for NCAs that need it, focusing on EMA Secretariat areas of excellence

For all NCAs we should work as a team to ensure

- Excellent science
- Excellent legal and regulatory outcomes
- Excellent information provision and communication
- Robust public health protection and promotion



Future

- Recommendation 15: EMA Secretariat should alleviate the administrative burden for scientific assessors when scientific complexity of a dossier justifies it

Team for integrated working

- Excellent legal and regulatory advice / support in assessments and opinions
- Excellent information provision and communication
- Excellent provision of /access to data and information



Future

- Recommendation 16: EMA Secretariat should continue putting specific efforts in quality assurance procedures, to guarantee the appropriate level of quality and consistency of EMA outputs

Team working for quality assurance including summarising, peer review function, leading to:

- Excellent science
- Excellent legal and regulatory input
- Excellent information provision and communication
- The most robust decision-making



Future

- Recommendation 24: EMA and NCAs should reinforce their coordination in all IT-related projects in order to facilitate the emergence of a European IT architecture

EMA has key role as the hub of the network:

- Excellence in IT meeting the challenges of new information technologies
- Excellence in data management, embracing globalisation
- Excellent data and information provision, meeting the expectations of stakeholders
- Research and improve the methods of information technology and data and information management



Future

- Recommendation 28: EMA should keep the lead on harmonising pharmacovigilance procedures and tools at the European level

23 June 2010

Agreement on new Pharmacovigilance legislation under the Spanish Presidency



Future

- Recommendation 30: Explore the potential impact of recent scientific evolutions on EMA activities
 - Gather intelligence on scientific evolutions
 - Identify expertise on scientific evolutions
 - Foster excellence in the sciences and their regulatory impacts
 - Meet the challenges of:
 - new science
 - new product technologies
 - new information technologies
 - Research:
 - Identify the research questions and identify challenges including those crossing product boundaries
 - Research the methods of regulatory science and technology



And finally.....

- Identify synergies to reinforce the networking model
 - In terms of expertise - the best man or woman may be at an NCA *or* EMA secretariat
 - In terms of best placed:
 - Those closest to the citizens are at the NCAs
 - Those best placed to give EU added value *may* be EMA secretariat
 - The past does not have to be the future
 - The world is evolving – we need to evolve also



And finally.....

- Strong public health promotion and protection requires a strong EU Regulatory network:
 - Depends on a strong EMA secretariat:
 - The salt and pepper that makes the meal taste good
 - The oil that makes the machine run smoothly
 - Synergies, team-work, excellence

Thank you for listening!