



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Session 2: What can already be improved following the evaluation of the Agency and the Network (without changing the legislation)

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An agency of the European Union





Drivers for improvement

Demand on resources

Complexity: architectural, interactions



Activity areas to address these two drivers

1. Efficiency of the network
2. Reinforcing quality and consistency of opinions
3. Reinforcing the network between assessors and staff



Efficiency of the network



Improving efficiency of processes

Apply internationally accepted methodologies for process improvement

- Already used by EMA and several NCAs to improve internal processes
- Extend to more processes
- This will include Committees and Working Parties
 - work with Committee and WP members, and NCAs



Virtual meetings vs. face to face meetings

- Guidance on which types of meetings and types of attendance could be virtual
- Targets to reduce face to face meetings



Working parties: efficiency

- Avoid duplicating WPs: concept of one WP serving several committees
- Has impact on membership
 - Expertise vs national membership
 - Cross membership
 - E.g. vaccine WP



Planned resource management within the network

- Considered of importance in the conference
- EMA delivers regular input to HMA
- Further reflection is needed
- HMA resource group?
- Level of information and data required



Multi national assessment teams

E&Y proposal

- Conference: 'further explore' feasibility
- Pressure on resources
- Define priorities and constraints
 - e.g. referrals - less issues in post marketing authorisation stage



Reinforcing quality and consistency of opinions



Quality and consistency of opinions

Drivers:

- Initiatives on better quality of opinions (with the EC)
- Initiatives on more clarity of opinions (with the HTA)

EMA secretariat

- Technical, scientific and administrative support (Art 56(1)(e))
- The new pharmacovigilance legislation gives new tasks

There is a need to:

- Further clarify the role and responsibilities of EMA secretariat
- Strengthen the team working concept: committee members, rapporteurs, their teams of assessors, experts, secretariat



Coordination between committees

- More committees
- Coordination is more complex
- Three pillars:
 - Executive Director
 - The EMA secretariat (Art 56(1)(e))
 - Cross membership concept
- Actions
 - Reinforce complementarities between the three pillars
 - Effective cross-committee membership role to deliver communication and coordination
 - Standing point on each committees' agenda; Monitoring



Involvement of civil society

- Value judgement by patients (COMP, PDCO)
- Expand to CHMP activities
 - SAGs, scientific advice, marketing authorisation opinions
- Public hearings
 - Pharmacovigilance legislation
 - Apply the concept to other committees in the future?



Reinforcing the network between assessors and staff



Greater exposure of NCA staff to European procedures and EMA staff to NCA work environment

Adapting the END programme

- More short term visits from NCAs colleagues
- EMA colleagues to national agencies (e.g. fellowships)



In Summary

- Improving efficiency of processes
- Virtual meetings
- Working parties
- Resource management within the network
- Multi-national teams
- Quality/consistency of opinions and EMA secretariat
- Coordination among committees
- Involving the civil society
- Exchange of staff: NCA to and from EMA