Conference on the outcomes of the evaluation of the European Medicines Agency (EMA)
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European Medicines Network

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EMA was built on, and remains embedded in, a European network with national competent authorities (NCA)

- A European Agency entrusted with tasks for which centralised evaluation and decision making can bring added value ;
- National agencies provide input on centralised matters through their contribution, for assessment as well as for inspection = continuous co-production between EMA and NCA, backed up by the collective skills of NCA ;
- Europe-assessment has thus been mainly meant as the outcome of the work of a network of agencies, and not primarily as the sum of individual expertise selected from the centre and apart from NCA ;

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A pragmatic and productive concept which has proven itself

- **It has made it possible to manage risk / benefit assessments in a reasonably consistent way ;**
- **It has succeeded in both receiving innovation and managing the move towards generics, at paces and according to procedures that vary from one country to another ;**
- **It has managed to cope with challenges (Cerivastatine, Vioxx, etc.) and in drawing some lessons with regard to its operation (improved post-AMM surveillance –progress with regard to transparency, etc) ;**
- **It has remained fundamentally 'win-win': more of Europe with due account of national responsibilities, progressive strengthening of the EMA without scientific impoverishment/weakening of national agencies ;**
- **It has secured both a robust collective assessment capacity and a sustained commitment of many NCA in the fulfilment of EMA tasks ;**

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A system that has now to address significant difficulties

- **Incremental expansion from 15 to 27 countries (indeed 30 when EEA states are included) has altered the original conditions of the initial model : a much greater challenge to achieve homogeneity within the network ; a need to promote participation of more NCAs in european tasks, with more diversified types of contributions ;**

- **Recent or imminent accumulation of legislative changes to be taken on board ;**

- **By contrast, inconsistent evolution of resources: sustained, and rightly so, at the centre (doubling of volume in 5 years in the case of EMA), very unequal at national level, depending on the intensity of constraints on public management; some new tasks have not been matched by adequate or even any resources (pædiatrics, plants, etc.) ;**

- **In this context, it may become sometimes difficult to find (co-) rapporteurs on a voluntary basis for specific tasks**

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A widespread awareness of the need to consistently meet those challenges

- **EMA reflections within the framework of the Road Map ;**
- **HMA analyses on resources and more recently preparation of Strategy Paper N° 2 ;**
- **Ernst and Young Report, putting EMA evaluation in the broader perspective of the operation and evolution of the network ;**

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Some fundamentals of the resources equation should be borne in mind

- **Increasing the level of human resources available within the network proves increasingly difficult, due both to stricter public workforces policies in many countries and to limitations affecting the availability of external expertise (shortages in some areas, tightening of rules pertaining to conflicts of interests) ;**
- **Persisting obligation for NCA to simultaneously fulfil their tasks at three levels : national assignments with public health accountability, coordinated work for non-centralised domains such as MRP/DCP or clinical trials, contribution to EMA activities ;**

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Need to be both pragmatic and creative to reach the best possible use of existing resources without entirely giving up efforts to get additional resources

- **Avoiding unnecessary duplication of work ;**
- **Promoting work sharing ;**
- **Developing explicit and planned resource management ;**
- **Fostering prioritisation on the basis of analysis of relative risk and more broadly relative public health added value of various actions ;**

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Possible ways of revamping the way NCA contribute to centralised tasks : three ideas to be discussed (1)

1 - Developing joint assessment teams for rapporteurships ;

- **Would allow involvement of additional NCA that have the necessary skills to take in charge part of the assessment (example: pharmaceutical quality) for which another NCA isn't well equipped or has no available workforce at some stage ;**

- **Necessary conditions to secure feasibility and sustainability of such an approach : need of a coordinator NCA accountable before EMA, probably no more than 3, if not 2, NCA involved, clear arrangements to secure post-authorisation work…**

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Possible ways of revamping the way NCA contribute to centralised tasks : three ideas to be discussed (2)

2 - Developing virtual meetings, with the support of systems such as vitero : progress already achieved during the last year, but still room for progress ;

3 - Encouraging on a voluntary basis cooperative arrangements between NCA whereby one NCA is mandated to represent one or two other NCA during some scientific meetings, and then shares information ;

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Conclusion

- **Participants are invited to discuss the above-mentioned ideas;**

- **… or any other idea that may produce time and energy saving at a time where scientific and regulatory workforce is scarce with regard to ever increasing workload !**