The Networking Medicines Agencies in Europe

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Current system in the medicines field

- Current system introduced in 1995, the so-called New System
- Introduced the centralised and the Mutual Recognition procedure for granting of Marketing Authorisations
- Networking model based on participation of MS and national experts in the different procedures
- Binding procedures and decisions were established

Centralised procedure

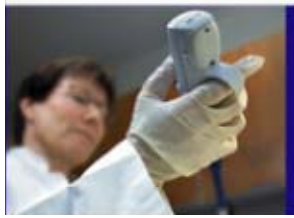
- Innovative medicines and biotech products
- A Rapporteur and a Co-Rapporteur from MS are appointed to make the evaluation of the dossier.
- CPMP (now CHMP) and CVMP adopts ”binding” opinions in the sense that this opinion forms the basis for a later Commission decision.
- Marketing Authorisations granted are directly applicable in all MS

Forums centralised procedure

- Many groups form the body of the centralised procedure, all co-ordinated and supported by the EMEA:

  CPMP
  CVMP
  COMP
  Pharmacovigilance WP
  Quality WP
  Safety WP
  Biotech WP
  Efficacy WP
  etc, etc

- Through these committees and groups the work is performed.
- The committees and groups draw on a broad range of national experts in many different fields.
- These persons and Committee/Group Members form the network of the European system in the Centralised Procedure



Mutual Recognition Procedure

- The Marketing Authorisation of the first MS is recognised by other MS (after short re-evaluation period)
- Demands common understanding and assessment of dossier - common trust between MS
- Demands efficient co-operation to be able to reach agreement within defined time limits

Forums of the Mutual Recognition Procedure

- First and foremost this procedure is co-ordinated and supported via the MRFG (Mutual Recognition Facilitation Group)
- It has been an informal group, established by Heads of Agencies
- With the Review texts it is now formalised under the name Co-ordination Group and given more power
- The network in this field consists of the national experts and regulators which co-operate in the procedure

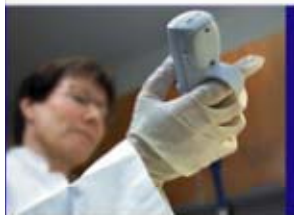
- Has been very efficient
- Results in the largest number of marketing authorisation in the EU
- Generics for the benefit of patients

Pharmacovigilance network

- After granting of Marketing authorisation post marketing supervision is performed, also in a networking model
- Pharmacovigilance working party -common evaluation of Adverse Reaction Reports and signals observed
- Common reaction to problems

Characteristics existing system

- The Regulatory system is based on networking and binding cooperation.
- Brings together the scientific resources of MS - high quality of evaluation and supervision
- Harmonisation of standards in MS
- Sound scientific assessments with a high quality, reviewed by other MS
- Dividing the work
- Trustworthy time-limits for the approval procedure



Networking other areas

- Regulatory and legal co-operation is performed via different working groups
- Harmonisation of interpretation of Community legislation is the object
- Enforcement - new area for co-operation
- Clinical Trial Facilitation Group
- Advice and assistance on ad hoc-basis from agency to agency

Preconditions for networking

- Needs a common ground in order to work
- Harmonised legislation and guidelines to create common interpretation of legislation
- This has been done to a very large extend in the medicines field
- Forums where to meet and exchange views
- Clear responsibility
- Support from the agencies behind the experts in order to ensure consistency in handling the different tasks

Benefits from a networking model

- Possibility of participation on equal grounds for MS
- Participation by MS on the level chosen by the MS
- Broad range of experts of high quality
- Having the relevant expertise at hand
- Reliable and sound assessments and opinions
- Trustworthy decisions to be followed at national level
- Develops the quality in the work (assessment and post marketing handling) for all parties involved

Future Regulatory Environment - challenges to be met

- Best quality and robustness of scientific assessments will be key issue
- New technologies - innovative medicines
- Transparency
- Co-ordination of work
- Consistency of assessments across applications - Scientific and Regulatory memory
- Further development of expertise in assessment and post marketing activities

Vision of networking

- To make the best use of the different skilled “brain cells” in Europe
- Create a well functioning network without making a tangle