Lessons from the EMA and the EU Network of National Regulatory Authorities

Dr. Ian Hudson

Former CEO MHRA, member of EMA Management Board and HMA Management Group.

Now Senior Adviser, Integrated Development, Bill and Melinda Gates Foundation
EU: The players

• The EU Commission
• EMA
• Heads of Agencies (HMA)
• Member States (28)
Shared responsibilities (1): 4 parties

- **Commission**: Legislation, Licensing Authority for Centrally Authorised products; negotiation of international agreements

- **EMA**: Centrally authorised products; PV; arbitration for non-EMA procedures, scientific advice, coordination of inspections; guidance; overseen by Management Board which meets 4x per year
Shared Responsibility (2)

- **HMA**: Coordination/oversight of non centralised procedures/non EMA activities, discussion on policy, discussion on implementation of legislation etc, meets 4x per year
  - Coordinated by HMA Management Group

- **Member states**: Clinical trials, scientific resources for EMA scientific procedures, national/decentralised/mutual recognition procedures, inspectors, PV, enforcement, scientific advice, particularly very early stages, innovation offices, legal status, classification
Shared Responsibilities

• Operate as effective single network
• Single overarching network strategy for 5 years, then EMA and HMA Multi-Annual Work Plan
• Extensive peer review across network, joint audit programme, benchmarking of performance across Agencies.
• Many opportunities for Heads to meet and build relationship – shared goals
Authorisation procedures

- **Centralised** – run by EMA – Biotech, Biosimilars, most NAS, generics of CAP.
  - Application to EMA, Rapporteurs assigned (MS) who conduct assessment [based on best available expertise], discussed at scientific committee CHMP, scientific opinion transmitted to Commission who issue authorisation applicable in all member states.

- **Decentralised** – generally older medicines, most generics: Company selects Reference Member State who runs procedure; other MS review and provide assessment at 2 stages alone way, harmonised decision making (or arbitration); CMDh; results in national licence.

- **Mutual Recognition** - once approved by one MS, others review and recognise (or arbitration); CMDh; results in national licence.

- **National**
What works well

• Common legislation and guidance; full lifecycle approach
• Balance between all players (essential component)
• Scientific committees to discuss and agree assessment; Working parties of specific experts support
• Ability to set up technical groups to consider implications and prepare for new technologies/approaches (big data, combination products)
• Access to large amount of scientific expertise throughout EU; extensive use of external experts nationally and internationally
• Key role for MS – indeed role increasing
• Fixed timings for all procedures
• MS varying in extent of contribution
• Fee based structure
• Evolution of system
Areas to improve

• Speed – procedures, changes to legislation
• Flexibility
• Need for increased regulatory tools for future
• Different approaches for devices, challenges for combination products/companion diagnostics
• Healthcare provision varies between MS, therefore some types of procedures difficult (legal status change)
• Fees and funding
• Broader contribution from more MS